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86-385

No. 86-

Supreme Court, U.S.
FILED
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JOSEPH F. SPANIOL, JR.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

DAIG CORPORATION,

Petitioner,

vs.

MEDTRONIC, INC., and
MEDTRONIC PUERTO RICO, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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August 29, 1986

1986—Northwest Printing Co., 3010 2nd St. No., Minneapolis, MN 55411—588-7506

QUESTIONS PRESENTED

1. Does the standard for judging patent validity as a matter of law, and for obviousness determinations in particular, as approved by the Court of Appeals for the Federal Circuit, conflict with the standards established by this Court pursuant to Constitutional mandate?

2. Does the decision of the Court of Appeals for the Federal Circuit affirming patent validity where a change to a known material for its known properties represents the only alleged advance over the prior art conflict with the decisions of this Court in *Hotchkiss v. Greenwood* and *Graham v. John Deere Co.?*

3. Can commercial success properly be found to exist in support of a conclusion of nonobviousness where the commercially successful embodiment is not disclosed in the patent, and the requisite "*nexus*" is thus lacking?

4. What is the proper scope of appellate review on the obviousness issue, and has the Court of Appeals for the Federal Circuit fully and fairly discharged its duty in that regard when it relies entirely upon the "clearly erroneous" standard under Federal Rule of Civil Procedure 52(a) in ruling on the legal question of patent validity with respect to the issue of obviousness?

Concurrent Petitions Before the Supreme Court of the United States Having Closely Related Issues

This Court's attention is directed to the petition for a writ of certiorari to the United States Court of Appeals for the Federal Circuit naming Eastman Kodak Company as Petitioner in *Eastman Kodak Company v. Polaroid Corporation*, File No. 86-96. That petition was filed on or about July 23, 1986. It presents closely related questions as to the conflict between the current standards applied by the Federal Circuit in determining patent validity and the standards set by this Court and the Constitution. Important public policy considerations arise from that conflict.

Statement Pursuant to Rule 21

At trial, this case was consolidated with the case of *Pacesetter Systems, Inc. v. Medtronics, Inc. and Medtronics Puerto Rico, Inc.*, since it contained similar issues and pertained to the same patent. Subsequent to trial, but prior to the dismissal of their appeal, Pacesetter Systems, Inc. became Siemens-Pacesetter, Inc., an affiliate of Siemens, A.G. a corporation of the Federal Republic of Germany.

Statement Pursuant to Rule 28.1

Daig Corporation does not stand in the position of parent, affiliate, or subsidiary to any other corporations.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Petitioner Daig Corporation (hereafter "Daig") respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Federal Circuit in the above entitled cause.

OPINIONS BELOW

The opinion of the Court of Appeals for the Federal Circuit (A-1) is reported at 789 F.2d 903, 229 USPQ 664 (Fed. Cir. 1986). The opinion of the District Court following trial (A-12) is reported at 611 F. Supp. 1498, 227 USPQ 509 (D. Minn. 1985), and its opinion granting a preliminary injunction (A-105) is reported at 221 USPQ 595 (D. Minn. 1983).

JURISDICTION

Federal jurisdiction in the District Court for the District of Minnesota was originally premised upon 28 U.S.C. §1338. The final judgment of the Court of Appeals for the Federal Circuit was entered on April 30, 1986. On June 10, 1986 an Order was issued denying a petition for rehearing, and the suggestion for rehearing *in banc* was denied by Order dated July 3, 1986. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article I, §8, clause 8 of the Constitution and §103 of the Patents Act, 35 U.S.C. §103.[1]

STATEMENT OF THE CASE

The Court of Appeals for the Federal Circuit was established in 1982 and was granted exclusive jurisdiction over appeals in patent suits from the several federal district courts pursuant to 28 U.S.C. 1292(c). In reviewing such cases it is the Federal Circuit's responsibility to ensure compliance with the Constitutional mandate and statutory standards for patentability. *Anderson's-Black Rock, Inc. v. Pavement*

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[1]Constitution of the United States, Article I, Section 8, clause 8

The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

35 U.S.C. §103. Conditions for patentability; non-obvious subject matter.

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. . . .

Salvage Co., 396 U.S. 57 (1969). This Constitutional mandate and the statutory standards "may not be ignored." *Graham v. John Deere*, 383 U.S. 1, 6 (1966) (*Graham*).

This case raises significant questions concerning the manner in which the Federal Circuit has modified the standards for patentability and obviousness which this Court set forth in *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850), and *Graham v. John Deere, supra*, and as mandated by the Constitution. This case also displays the impropriety and harm in the Federal Circuit's recent abdication of judicial responsibility for appellate review of patent appeals through its misuse of the "clearly erroneous" standard in Federal Rule of Civil Procedure 52(a).

Particularly, this case presents an opportunity for this Court to evaluate the balance to be drawn between the presumption of patent validity which has promoted confidence in the patent system, and the threatened deterioration of that system which will eventually result if patents continue to be allowed and affirmed merely satisfying the technical test for novelty without rising to that level of 'invention' identified by this Court as necessary to justify the privileged position a patent represents. Such patents do not satisfy the Constitutional mandate "to advance the Progress of . . . the useful Arts." Art. I, §8, Cl. 8.

Technical Background

The patent-in-suit, U.S. Patent No. 3,927,501 to Citron (Ex.-1), relates to endocardial pacemaker leads. Pacemaker leads connect a heart pacemaker to an electrode. The lead is in the form of a flexible catheter which is inserted transvenously into the heart. The lead contains a wire conducting coil which connects the pacemaker to the electrode and

which is encased in a silicone rubber insulating sheath. The electrode supplies a stimulating electrical pulse to the heart.

Transvenously introduced endocardial leads had been in use for many years prior to the '501 patent. Myocardial leads are affixed to the outside of the heart or myocardium. Endocardial leads are affixed to the inside wall of the heart or endocardium. Prior art retention or anchoring mechanisms for the electrode included a helical screw which pierces the heart wall; a conical, silicone rubber wedge (wedge-tip); and one or more rearwardly projecting barbs or tines resembling a grappling hook (tined lead). Both the wedge tip and metal tined leads of the prior art were retained in place by catching in the tentacle-like bundles of muscle fiber (trabeculae) lining portions of the endocardium.

Medtronic had been selling its standard wedge-tip leads for several years prior to developing its "Grapnel" lead having long tines projecting rearwardly from the electrode tip at an acute angle from the body of the electrode.

An outside consultant, Dr. Nicholas Smyth, suggested to Citron that the tines be shortened so the electrode tip could reach the wall of the right atrial appendage (upper heart chamber) without interference from the long tines. This suggestion was included by Medtronic along with several other changes in the Grapnel lead to form what became known as the "Smyth J-atrial lead." Medtronic then abandoned the Grapnel lead in September of 1973, and adopted the improved Smyth J-atrial tined lead.

The success of the Smyth *atrial* lead brought about interest in a tined *ventricular* lead. In 1976 Medtronic began marketing its Model 6950/51 ventricular lead having long tines as shown in the Citron '501 patent. The 6950/51 lead was not a commercial success because the tines were simply

too long and located too near the electrode tip. The tines contacted the myocardium and acted as resilient springs to push the electrode tip away from its ideal pacing position at the apex of the right ventrical (lower heart chamber).

Physicians reported difficulty implanting the 6950/51 lead to Medtronic, and Medtronic reduced the length of the tines from 10-15 millimeters to approximately 2.5 millimeters. The modified lead was then introduced as the Model 6960/61 tined lead. The 6960/61 lead, however, also contained for the *first* time several new features, including the Multi-Filar conductor coil and the ring-tip electrode, each of which had proven to have many independent merits.

The short, stubby rubber tines of the 6960/61 lead were *not* disclosed in the '501 patent. Nor had the other features of the 6960/61 lead been incorporated in the prior long-tined version. As Medtronic's own report[2] indicated, the 6950/51 lead was merely a redesign of its prior wedge-tip lead, the *sole* difference being the replacement of the silicone rubber wedge with silicone rubber tines used for the same purpose: lodging in the trabeculae of the heart.

The Citron '501 Patent and Prosecution History

In initially rejecting the claims of Citron's patent application, the patent examiner relied upon a patent to Collett (Ex.-39) in combination with a journal article by Schaldach (Ex.-20). Schaldach expressly disclosed finger-like tines at the tip of a pacemaker lead which anchored in the trabeculae and held the electrode in proper pacing position. The patent attorneys for Medtronic argued that the metal tines in the Schaldach article presented a potential danger of

[2]4-Month *In-Vivo* 6950 Tined Endocardial Ventricular Lead Study; (Ex.-45).

perforating the heart wall. They asserted that Citron's tines were made of silicone rubber and therefore could not pierce the heart wall.

Claim 1 of the Citron application[3]—the only claim at issue—was then amended to specifically define the tine means as being ". . . *entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue. . .*" The Citron '501 patent was finally allowed based upon the inclusion of this limitation.

Opinion of the District Court

After a bench trial, the District Court concluded that the '501 patent was valid and infringed, and entered its judgment accordingly.

In its opinion, the court recited the procedural posture of the consolidated suits, and recapitulated much of the peripheral evidence presented at trial. Though the court reiterated much of the factual history, it excluded from its opinion such vital evidence as Medtronic's own report indicating that the '501 tined lead was a redesign of their prior art wedge-tip lead. (Ex.-45). This and other omissions are discussed herein.

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[3]Claim 1 of the '501 patent is:

1. In an endocardial lead of the type having an electrical conductor encased in a material which is generally inert to body fluids, the conductor terminating at an exposed electrically conductive electrode tip, the improvement which comprises: nonconducting tine means extending from said encasing material and away from said tip from a location adjacent said tip for cooperating with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said encasing material and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids. (Ex.-6).

In making its conclusions of law on the issues of obviousness and validity, the District Court reviewed each of the prior art references at length, but again failed to mention several critical points contained in the references. It did not indicate that Rasor taught nonconducting tines placed on the tip of a pacemaker electrode. It erred in finding that the Schaldach tines were intended to actively attach by piercing heart tissue, where in fact Schaldach describes in language almost identical to the abstract of the '501 patent how the tines catch in the trabeculae.

While the District Court restated the elements of the test for nonobviousness outlined in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), it made several legal errors which led it to an erroneous conclusion concerning obviousness. Most significantly, it failed to recognize the change of material from metal to silicone rubber in the previously known tines as the only difference over the prior art. This error stemmed from the court's misapprehension of the problem facing Citron. Further, the District Court analyzed each prior art reference in a §102 sense to determine what it alone taught, but failed to mention what *any* particular combination of references might suggest, such as Rasor combined with Fountain. Although the court mentioned the references 'alone or taken as a whole,' it failed to give any consideration to what the prior art 'taken as a whole' might suggest to one of ordinary skill in the art as to the selection of a material for the tines which would not damage heart tissue.

Finally, the District Court failed to identify the merits of the '501 patent, and did not relate the commercial success of the 6960/61 lead to the features or structure disclosed in the '501 patent. In fact, the court was unable to

relate any features of the commercially successful 6960/61 lead—the short, stubby nature of the tines placed close to the electrode tip, the Multi-Filar coil, the ring-tip electrode —to the '501 patent, since none of these features were disclosed in the '501 patent. The court found, to the contrary, that extensive experimentation would be necessary to arrive at a commercially successful lead from the '501 disclosure.

Opinion of the Court of Appeals

The Court of Appeals provided a brief background in which it outlined the same 'patented structure' and misinterpretation of the 'invention' provided by the district court.

The Court went on to state the modified test for obviousness which it has adopted, in which the secondary considerations such as commercial success, properly relevant only to close questions of obviousness, are incorporated as mandatory considerations.

The Court then turned its attention to the district court's evaluation of the problem, which it simply quoted, and to the sufficiency of the District Court's findings under Rule 52(a). The Court stated that while Rule 52(a) does require specific findings of fact to be stated, it is not so demanding as to require the District Court to articulate every permutation and combination of prior art teachings. The Court did not state its views as to whether the failure to mention *any* combination of prior art, or to consider what the prior art references *together* might suggest, would constitute error fatal to the ultimate conclusions on nonobviousness and validity.

Finally, the Court addressed the question of commercial success by quoting nearly a full page of text from the district court opinion unrelated to the issues raised on appeal

of whether a *'nexus'* was established with the merits of the patented invention, and whether commercial success should properly be considered in this case. The Court made no further comment on the issue of commercial success.

REASONS FOR GRANTING THIS PETITION

I.

IN FAILING TO TRULY CONSIDER THE COMBINED TEACHINGS OF THE PERTINENT ART, THE COURTS BELOW DID NOT APPLY THE PROPER STANDARD FOR OBVIOUSNESS

The opinion by the Court of Appeals is flawed by its misconception of the nature and scope of the alleged "invention" of the '501 patent. That is indicated by the Court's description of the patented structure as "a lead having a plurality of pliant, nonconducting tines which extend away from an exposed metal electrode tip and cooperate within the heart to hold the exposed electrode tip against the heart wall. . . The tines provide this fixation without damaging or penetrating the heart tissue." No mention is made of the critical limitation on which claim 1 was allowed, namely, ". . . tine means . . . entirely of a pliant material . . . sufficiently pliant to prevent penetration of said heart tissue." The patented structure as described by the Court of Appeals is fully described and anticipated by the Rasor '864 patent (Ex.-8) with respect to the Fig. 12 embodiment. Both of the lower courts apparently reached the erroneous conclusion that Medtronic invented tines for holding the electrode of a pacemaker lead in pacing position against the wall of the heart. The prior art of record shows that not to be the case.

The Rasor '864 patent discloses in Fig. 12 (Ex.-18) and describes in columns 9 and 10 (Ex.-13), a lead embodiment with electrodes for use with conventional pacemakers. That embodiment discloses as the attachment means for the electrode for securing it in the heart a pair of radiating fingers or tines which do extend rearwardly at an acute angle from the electrode assembly. Those fingers are described as being flexible and bendable so as to be able to be compressed down against the body of the electrode assembly during transvenous implantation. The Rasor tines are thus pliant. Rasor further discloses with respect to the "lead" embodiment of his pacemaker electrode device as shown in Fig. 12 that the unipolar (single electrode) version of such a lead would have a single lead wire connecting inside the body of the device directly to the electrode tip. Thus, as Medtronic's expert, Dr. Maloney, testified, the tines would be nonconducting in such an embodiment.

Rasor is lacking as a full anticipation of the subject matter of claim 1 of the '501 patent, and thus as a bar to patentability under 35 U.S.C. §102(b), *only* because he does not expressly disclose that his tines are made of a material sufficiently pliant to prevent penetration of heart tissue.

The Schaldach article (Ex.-25) discloses a pacemaker electrode having fine wire tines. The disclosure is made that the tines, ". . . can be firmly anchored between the trabeculae[4] of the right auricle" in order to hold the electrode tip in permanent contact with the atrial endocardium. That is the same type of passive fixation mechanism disclosed in the '501 patent with respect to the claimed pliant tines.

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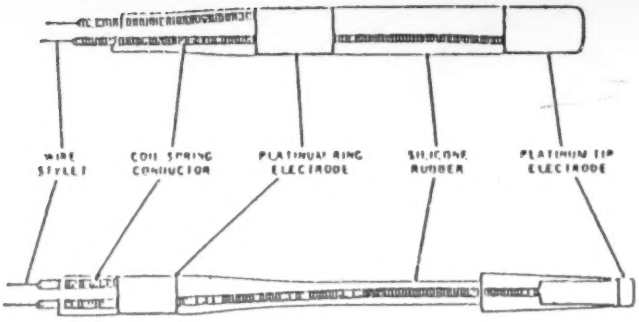
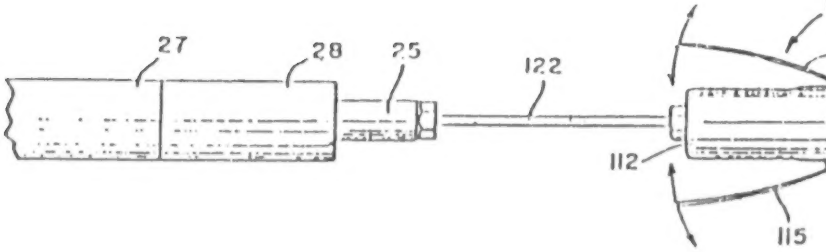
[4]The trabeculae comprise latticelike structures of small bundles of muscle fibers found primarily in the right ventricle of the heart, and to a lesser extent in the right atrial appendage.

BEST A

Standard tip and Flange-tip Bipolar Endocardial Leads



Rasor



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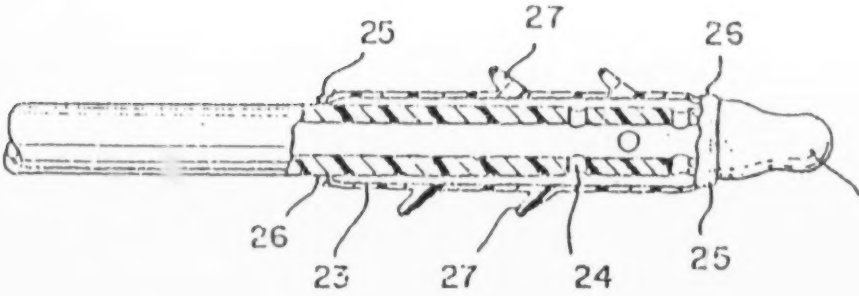
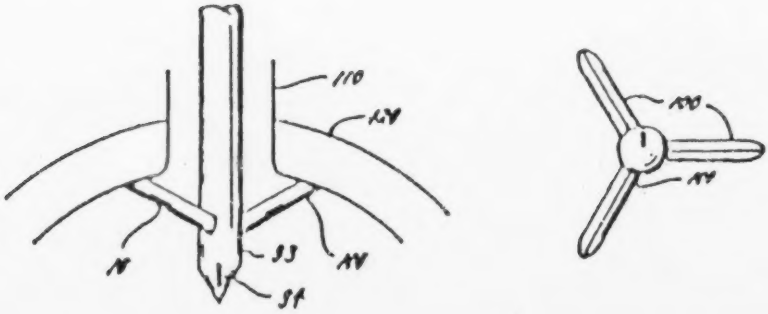


Fountain



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The Fountain patent (Ex.-30), not cited by the Patent Office, discloses a plurality of flexible, silicone rubber tines on the distal or remote end of a catheter inserted transvenously into the heart. The flexible projections or tines are described as being bendable upwardly and flexible to avoid scarring or damage to the walls of the vascular system. The Fountain tines are utilized to hold the distal tip of the catheter within the atrium of the heart for the purpose of draining fluid into the heart.

The patent to Klieman (Ex.-34), also not cited by the Patent Office, discloses an embolectomy catheter utilized for removing blood clots from vessels and arteries. It has at its tip a plurality of integrally formed "barbs" approximately one millimeter in length which extend away from the tip at an acute angle, preferably 45 degrees. Those tine projections of Klieman are further described as being ". . . rounded and sufficiently flexible to avoid damage to the vessel, but are firm enough to hold on to the clot."[5]

The Porstmann article (Ex.-27) discloses that the metal tined devices of Schaldach were successfully implanted in a number of patients without any dislocation of any of the anchored atrial electrodes.

Thus, the true question presented under 35 U.S.C. §103 is whether it would have been obvious to those skilled in the art to make the previously known metallic tines of Rasor and Schaldach out of a pliant material, such as silicone rubber, which would totally avoid penetration of heart tissue and injury to the vascular system.

In affirming the District Court without comment on the question of the teachings and suggestions reasonably to be drawn by those skilled in the art from the aforesaid prior art as to the use of a pliant material for the previously

[5]Figures from the prior art references discussed herein are displayed on the facing page for convenient reference.

known retention tines on pacemaker leads, the Court of Appeals has erroneously sanctioned the lower court's improper approach to obviousness. The approach was contrary to the decisions of this Court. It comprised only the detailed examination of each prior art reference separately as to inventive features disclosed. No comments or discussion whatsoever were presented by either of the courts below with respect to the impact of the combined teachings of the prior art on the ultimate legal question of obviousness based on the change of the tine material.

As this Court has held, the prior art as a whole must be considered when determining obviousness. *Dann v. Johnston,* 425 U.S. 219, 230; 189 USPQ 257, 261 (1976). *See* also, *Orthopedic Equipment Co., Inc. v. United States,* 702 F.2d 1005, 217 USPQ 193 (Fed. Cir. 1983).

Petitioner did not seek below and does not seek now the articulation of "every imaginable permutation and combination of prior art teachings." (A-7) The error below compelling review by this Court was that neither lower court addressed any combination of references, much less the combination of Fountain with Rasor or Schaldach. Fountain clearly suggests making the tines on the Rasor pacemaker lead out of pliant material such as silicone rubber to avoid damage to the vascular system.

The District Court did make a thorough analysis of the Fountain patent. However, its error, affirmed by the Court of Appeals, was in totally focusing on the Fountain invention, rather than on what Fountain might reasonably suggest when considered together with the Rasor patent as to nontissue damaging catheter retention in the heart. *EWP v. Reliance Universal Inc.,* 755 F.2d 898, 907, 225 USPQ 20, 25 (Fed. Cir. 1985); *In re Sovish et al,* 769 F.2d 738

792, 226 USPQ 771, 774 (Fed. Cir. 1985). The District Court emphasized that Fountain does not disclose how his pliant, silicone rubber tines could be used to hold the tip electrode of a pacemaker lead in pacing contact with heart tissue. (A-69). That is precisely the type of erroneous reasoning that conflicts with this Court's directives for appraising the prior art as a whole. *Dann v. Johnston, supra.*

A proper analysis of the prior art does not require that Fountain disclose tine means for holding the electrode tip of a pacemaker lead in pacing contact with the heart wall. Rasor, Schaldach, and the previously utilized wedge tip lead all establish as prior art how retention mechanisms such as tines and wedges can be used for such a purpose. As the Trial Court found, the relevant prior art embraces "catheterlike devices in general."

The question is whether the disclosure by Fountain of pliant, nontissue damaging silicone rubber tines for securing an intravenously inserted catheter in the heart would render obvious the use of such a pliant material for the very same purpose in making the previously known tines on pacemaker leads. The error of both the District Court and the Court of Appeals in failing to even recognize, much less address and consider that question, requires the review of this Court.

If such an erroneous approach to determining obviousness under 35 U.S.C. §103 is not addressed by this Court, precedents and guidelines for determining patentability will become established which are at absolute odds with the mandates of the Constitution and of this Court. The commercially damaging result will be that marginally innovative improvements will be given the stamp of approval for patent protection. Thus, unlawful monopolies will be

established in areas of technology that truly and properly belong within the public domain. *Graham, supra,* 383 U.S. at 5-10; *Dow Chemical Co. v. Halliburton Oil Well Cementing Co.,* 324 U.S. 320, 64 USPQ 412 (1945); *A & P Tea Co. v. Supermarket Corp.,* 340 U.S. 147, 87 USPQ 303, 305-306 (1950).

II.

THE COURT OF APPEALS ERRED IN AFFIRMING PATENT VALIDITY WHERE A CHANGE TO A KNOWN MATERIAL FOR ITS KNOWN PROPERTIES REPRESENTED THE ONLY ALLEGED ADVANCE OVER THE PRIOR ART

One basic rule of patent law expressed by this Court in 1850 is that a mere change in the material from which an article is constructed does not rise to the level of innovation required to qualify as an invention—and therefore be patentable—within the meaning of the Constitution. *Hotchkiss v. Greenwood,* 52 U.S. 248 (1850).

The rule in *Hotchkiss* has been followed and applied in a consistent manner by this Court.[6] That has been done for a reason. The admonition by this Court that something more than the work of the ordinary person skilled in the art must be present to justify the privileged position of a patent represents the well founded application of the Constitutional mandate "to advance the Progress of . . . the useful Arts." Art. 1, sec. 8, cl. 8; *Graham v. John Deere,* 383 U.S. 1 (1966).

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[6] *See, Hicks v. Kelsey,* 85 U.S. (18 Wall) 670 (1873); *Terhune v. Phillips,* 99 U.S. 592 (1878); *Garner v. Herz,* 118 U.S. 180 (1886); *Brown v. District of Columbia,* 130 U.S. 87 (1189); *Florsheim v. Schilling,* 137 U.S. 64 (1890).

In the case of *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486 (1876), this Court qualified that rule by stating that a change of material which is the product of "more than a mere substitution of one material for another" and more than "the exercise of mechanical judgment and taste . . ." may in *some* instances rise to the level of invention. 93 U.S. at 495.

This Court later explained in *Florsheim v. Schilling, supra* N.1, that in order to constitute invention, the change in material must give rise to a new function, or the change in materials must allow the known device to be used in a new way, method, or mode of operation. To merely substitute one known material for another to obtain its known benefits does not rise to the "dignity" of invention.[7] Rather, there must be some entirely unpredictable result or difficulty in making the product from that new kind of material, or some new function given to that material, in order to constitute invention (nonobviousness).

In this case, the prior art before Citron showed tines placed on the tip of a pacemaker lead and used for the same purpose Citron employed them in the '501 patent: catching in the trabeculae and holding the electrode in pacing position. The basic shape of Citron's tines is identically disclosed in the Rasor patent. The Schaldach article clearly discloses the identical *function* and operation of the tines:

> To maintain permanent contact with the atrial endocardium, *the electrode tip is provided with fine wire*

[7] *See*, for example, *United States Appliance Corp. v. Beauty Shop Supply Co.*, 121 F.2d 149, 50 USPQ 40 (9th Cir. 1941), *cert. denied*, 314 U.S. 680, 51 USPQ 546 (substitution of rubber for metal in a curling rod); and *Krause v. Coe*, 120 F.2d 717, 49 USPQ 427 (D.C. Cir. 1941) (substitution of rubber for leather in valve gaskets).

> *hooks* [*tines*] *so that it can be firmly anchored between the trabeculae of the right auricle* [*atrium*] . . .
>
> . . . *advancement of the electrode will release the wire hooks* [*tines*] *to anchor in the trabeculae* of the right atrial appendage, where P-wave potentials normally exceed 5 mV. *The placement is conventional in every regard.*
>
> Schaldach (Ex.-25) (Emphasis added).

The existence of tined leads was accepted. The only problem facing Citron in using such tines in his ventricular tined lead was selecting a soft and flexible material to replace the tines of rigid material so they would not accidentally pierce the tissue of the vascular system. His choice was the same silicone rubber which Medtronic had been using for many years to form the retention wedge on the wedge-tip leads.

The patent examiner did not have any prior art showing *tines* made of silicone rubber. The wedge-tip leads, used for many years by Medtronic and others to anchor an electrode in the trabeculae, were never fully made known to the examiner as having such an anchoring mode. The Fountain patent showing flexible rubber tines used specifically to retain an intravenously implanted catheter within the atrium was not known to the examiner. The examiner never focused on the silicone rubber wedge-tip leads used for many years by Medtronic and others. As noted in the Background herein, Medtronic considered its tined lead to be a redesign of its prior wedge-tip lead: a change in form substituting the silicone rubber tines at the same position on the electrode for the silicone rubber wedge. (Ex.-50). That developmental history was never made known to the examiner.

The amendment to claim 1 which Medtronic attorneys

advanced to overcome the prior art rejection emphasizes the *narrow* scope of Citron's purported advance over the prior art: making the tine means ". . . *entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue.*" The Citron '501 patent does not mention a range of flexibility necessary to achieve this result. This is because the single task left to Citron was making the tines from the *same* material known for years to have just such a property, and proven to be effective *for that purpose* both in the silicone rubber tines in Fountain and in Medtronic's own prior art silicone rubber wedge-tip leads.

Such a change to a material for the benefit of its known properties and for the same function and in the same type article in which it had previously been used does not rise to the level of invention which is premised on the Constitutional mandate, as established in the standards for patentability and nonobviousness by this Court in *Hotchkiss* and *Graham.*

The District Court's failure to recognize the true 'problem' faced by Citron resulted in its never applying this standard of patentability.[8] Lead dislodgement was never asserted as a problem to the Patent Office, and the Porstmann article clearly indicates that the Schaldach tined leads did not suffer from dislodgement.

As this Court concluded in *Graham,* ". . . the 1952 Act was intended to codify judicial precedents embracing

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[8]The trial court stated the problem as: "development of an endocardial pacemaker lead with a means of passive fixation to reduce the incidence of lead dislodgement in the ventricles and right atrial appendage and to lessen the risk of tissue penetration or damage in the veins and heart chambers." (A-55). *See,* 789 F.2d at 905, 229 USPQ at 667.

the principle long ago announced by this Court in *Hotchkiss v. Greenwood*, 11 How. 248 (1850), and that, while the clear language of §103 places emphasis on an inquiry into obviousness, the general level of innovation necessary to sustain patentability remains the same." 383 U.S. at 3. In referring to the statutory basis for the patent grant, this Court said "[n]or may it enlarge the patent monopoly without regard to innovation, advancement or social benefit gained thereby . . . Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available." Id at 6. It would be equally impermissible for the Federal Circuit to circumvent this Constitutional mandate by failing to enforce the appropriate standard for obviousness.

Affirming the validity of the Citron '501 patent in light of the most pertinent prior art—Schaldach, Rasor, Fountain, and Medtronic's own wedge-tip lead—casts doubt upon the continuing vitality of the standard of patentability established by this Court in *Hotchkiss* and reaffirmed in *Graham*.

While the Federal Circuit has reinforced the strong role of patents among the business community, continuing to affirm questionable patents which do not improve the art and constitute mere "shadows of shades of ideas"[9] will eventually have a detrimental effect upon the entire patent system.

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[9] *Atlantic Works v. Brady*, 107 U.S. 192, 200 (1882); *See*, Black, dissenting in *Goodyear Tire & Rubber Co., Inc. v. Ray-O-Vac Co.*, 321 U.S. 275, 60 UCPQ 386 (1944).

III.

THE LOWER COURTS ERRED IN THEIR APPLICATION OF THE FACTOR OF COMMERCIAL SUCCESS IN DETERMINING OBVIOUSNESS

Since, as pointed out above, the only difference over the prior art was in the change of material, the secondary considerations of alleged commercial success and long felt need improperly became primary factors in the obviousness analysis by the lower courts.

The error of both lower courts, showing strong conflict with the directives for a proper obviousness analysis established by this Court, was in elevating such objective evidence of secondary considerations to an equal standing with the three basic factual inquiries set forth in *Graham v. John Deere, supra,* and then in proceeding to consider all such factors simultaneously. That improper approach is indicated in the listing by the Court of Appeals of *four* factual inquiries to be made in assessing nonobviousness, with the secondary considerations being listed along with the other three basic *Graham* inquiries. *Medtronic, supra,* 789 F.2d at 904-5, 229 USPQ at 666 (A-5).

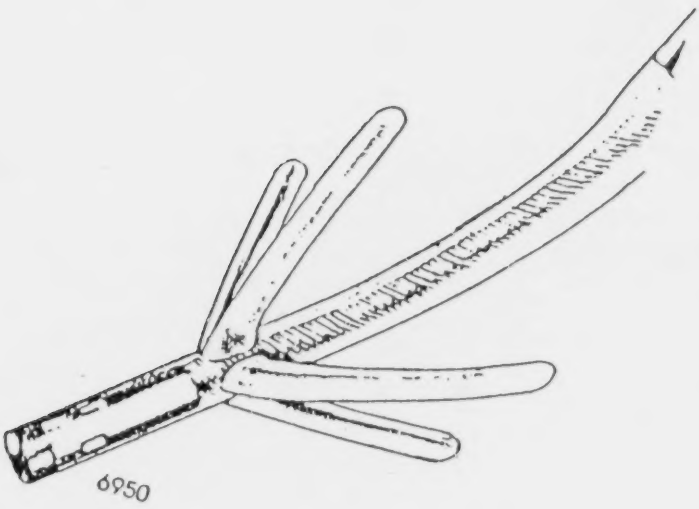
In *Graham,* this Court made it clear that the ". . . *basic factual inquiries* . . ." to be considered are the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. (Emphasis added). Significantly, after setting forth those factors, this Court proceeded in *Graham* to state that:

> "*Against this background, the obviousness or nonobviousness of the subject matter is determined.* Such *secondary* considerations as commercial success, long felt

> but unsolved needs, failure of others, etc., *might* be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries *may* have relevancy." *Graham, supra,* 148 U.S.P.Q. at 467. (Emphasis added).

In its subsequent decision, this Court affirmed that the three basic factual elements set forth in *Graham* are "the *central factors* relevant to any inquiry into obviousness." (Emphasis added). *Dann v. Johnston,* 425 U.S. 219 226, 189 USPQ 257, 260 (1976). Filling a long felt need and realizing commercial success are relevant *only* in close cases where the existence of patentable subject matter is truly in doubt. *Dow Chemical Co. v. Halliburton Oil Well Cementing Co.*, 324 U.S. 320, 64 USPQ 412 (1945); *Textile Machine Works v. Louis Hirsch Textile Machines, Inc.*, 302 U.S. 490, 36 USPQ 37 (1938). Commercial success without invention will not make patentability. *A & P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 153, 87 USPQ 303, 306 (1950). The approach of the Court of Appeals for the Federal Circuit in applying the "secondary factors" on an equal, initial factual inquiry basis with the three central factual inquiries set forth in *Graham,* in the instant case and in its other decisions, is in clear conflict with the directives of this Court. *See, Stratoflex v. Aeroquip Corp.*, 713 F.2d 1530, 1539, 218 USPQ 871, 879 (Fed. Cir. 1983); *Simmons Fastener Corp. v. Illinois Tool Works,* 739 F.2d 1573, 1575, 222 USPQ 744, 746 (Fed. Cir. 1984).

The District Court placed great emphasis on commercial success. The Court of Appeals did not independently appraise this secondary factor. It affirmed the lower court's findings by simply quoting large segments of the opinion



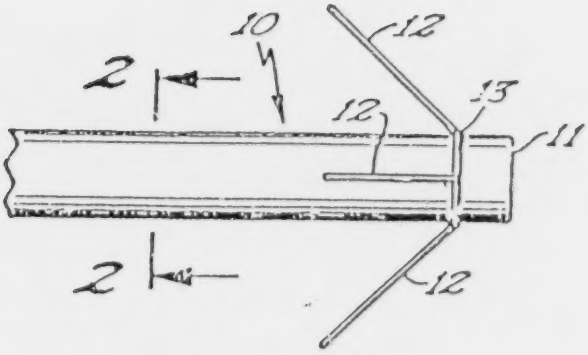
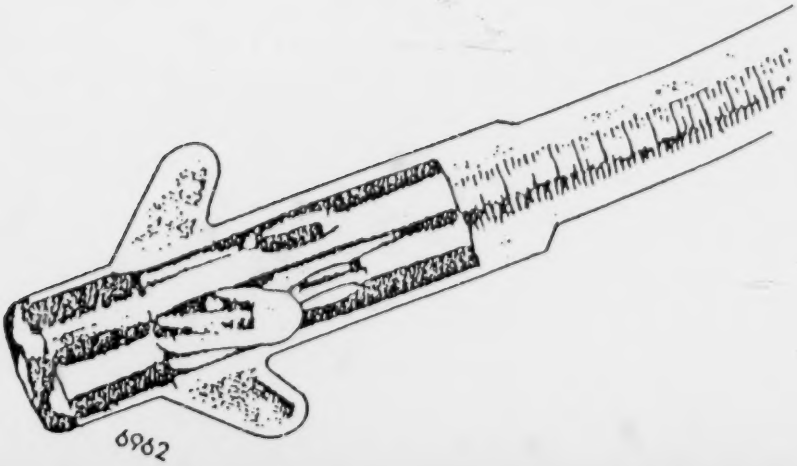


FIG. 1 OF '501 PATENT



below, without comment on the key legal question of the proper nature and extent of the *"nexus"* which must exist between commercial success and the patented subject matter. The Court of Appeals thus failed to carry out its full function of appellate review.

In order for commercial success to be properly applicable as a factor in the obviousness inquiry, the success realized must be directly attributable to the merits of the patented subject matter; i.e., a *nexus* must exist. *In re Vamco Machine & Tool, Inc.*, 752 F.2d 1564, 224 USPQ 617 (Fed. Cir. 1985); *Stratoflex, Inc. v. Aeroquip Corp., supra*, 713 F.2d at 1535, 218 USPQ at 879; *Cable Electronic Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1027, 226 USPQ 881, 887-888 (Fed. Cir. 1985).

The requisite *nexus* between the commercial success shown and the tined lead disclosed in the '501 patent was lacking. The only Medtronic tined lead found by the Trial Court to have been commercially successful, Model 6961/62, incorporates short, stubby tines close to the lead tip in a construction not disclosed in the '501 patent. The '501 patent discloses long, wirelike tines. Such tines were embodied in the first Medtronic ventricular lead, Model 6950, which the Trial Court expressly found not to have been successful. (A-77).[10]

The disclosure of the '501 patent provides no instruction to those skilled in the art as to the critical length of the tines shown to be essential for commercial success. Thus, there is no requisite *nexus* between the merits and advantages of the commercially successful short, stubby tines and

[10]Reproductions of the pictorial representations of the long tined 6950 lead, Fig. 1 of the '501 patent showing the relatively long, similar tines of the patent disclosure, and the short, stubby tined 6962 lead, as reproduced from trial exhibits, appear on the adjoining facing page 23.

the disclosure of the '501 patent. Such features are not *inherent* in the disclosure of the '501 patent as stated by the Trial Court (A-84).

The Trial Court's own findings on the question of the sufficiency of the disclosure of the '501 patent under 35 U.S.C. §112 *preclude* a finding of commercial success attributable to the tined lead disclosed in the '501 patent. That express finding was as follows:

> "The second way in which Pacesetter attempted to show that the '501 patent specification was not enabling was that it would take an unreasonable amount of experimentation to get from the patent specification to a working tined lead. Although some experimentation would certainly be necessary to go from the specification to a working tined lead, that experimentation would not be unduly extensive or unreasonable for a person skilled in the art. *If, however, a person would want to go from the specification to a commercially acceptable and marketable tined lead, then extensive experimentation would be needed.*" (A-89)[11] (Emphasis added).

The commercial success of a machine as "claimed" in a patent may be due entirely to later improvements or modifications to the invention as *disclosed* in a patent. Success based entirely on later improvements or modifications made to the invention disclosed in a patent, after extensive experimentation, is not pertinent to the nonobviousness of the advantages inherent in what is specifically disclosed in the patent. *In re Vamco, supra,* 752 F.2d at 1577, 224 USPQ

[11]In reproducing the Opinion of the Trial Court at 227 U.S.P.Q. 536, a printing error was apparently made. The above-quoted portion of the Trial Court's Opinion has been deleted from that report of the case. Page 89 from the original Memorandum Opinion of the Trial Court is reproduced in the Appendix at page 89, showing the correct version of the Opinion rendered by the Trial Court.

at 625, Fn 5 (Fed. Cir. 1985). This Court has also held that success achieved by an article subsequently developed by the patentee and fellow engineers by continuous experimentation over a period of years, cannot establish a patentable invention. *Marconi Wireless Telegraph Co. of America v. United States,* 320 U.S. 1, 57 USPQ 471 (1943).

In affirming on appeal, the Court of Appeals also erred with respect to the Trial Court's finding of a long felt need. The use of tines on pacemaker leads to reduce lead dislodgment had been accomplished and published by Dr. Schaldach in 1971 (Ex.-20), and recognized by Rasor (Ex.-8). The only alleged "problem" remaining in 1972 was that of making the previously known metal tines out of a material which would be sufficiently pliant to avoid penetration of vascular tissue. Implementing that step followed immediately in 1972, the year in which the alleged invention of the '501 patent was achieved.

Even assuming, *arguendo,* that a *nexus* does exist, the desirable benefits of commercial success and allegedly overcoming a long felt need, found by the District Court, may not properly establish patentability where, as here, there is a *prima facie* showing of obviousness based on the prior art. *Graham,* and *Dann v. Johnston, supra; Sakraida v. Ag Pro, Inc.,* 425 U.S. 273, 189 USPQ 449 (1976); *A & P Tea Co. v. Supermarket Equipment Corp.,* 340 U.S. 147, 153, 87 USPQ 303, 306 (1950). *Contra, Simmons Fastener Corp., supra* (Fed. Cir. 1984).

The subtests, properly constituting *secondary* factors, do not tip the scales of patentability where the differences from the prior art are rendered apparent by a prior art patent before the alleged unsuccessful attempts to solve the problem. It is irrelevant that no one chose to avail them-

selves of the knowledge stored in the Patent Office. *Graham, supra,* 148 USPQ at 474. That is precisely the situation in the instant case. The uncited Fountain patent (Ex.-30) renders apparent the use of pliant, silicone rubber tines on an intravenously inserted catheter to hold the catheter in the heart, without damage to the vascular system.

IV.

IN RELYING ON THE "CLEARLY ERRONEOUS" STANDARD OF RULE 52(a) THE COURT OF APPEALS HAS NOT FULLY AND FAIRLY DISCHARGED ITS DUTY TO REVIEW THE LEGAL QUESTIONS OF OBVIOUSNESS AND VALIDITY.

The Court of Appeals relied primarily on the "clearly erroneous" standard of Rule 52(a) in considering the ultimate legal determination of nonobviousness by the District Court. In so doing, it neglected to exercise its duty of appellate review as to whether the proper legal standards for obviousness were applied. In quoting large portions of the District Court decision, rather than providing independent review of the legal issues raised, the Court of Appeals did not carry out the proper scope of appellate review. Those legal issues involve the proper legal approach to evaluating the combined teachings of the most pertinent prior art, the determination of obviousness when the only advance over the prior art is a change of material, and the availability and application of commercial success as a factor in allegedly supporting nonobviousness.

The Court of Appeals viewed the question of whether the Trial Court considered the teachings of the prior art "as a whole" from the standpoint of the "adequacy of findings"

under Rule 52(a). (A-7). That was error. The scope and content of the prior art do represent underlying factual considerations; however, the manner in which the prior art is evaluated, and whether the teachings and clear suggestions of the most pertinent prior art references were fully considered in combination with each other, are matters involving the application of the proper legal standard for determining obviousness. In looking only to the "express and necessarily implied findings" of Judge Larson, the Court of Appeals erred in not even addressing the question of whether the correct legal standard for determining the question of obviousness was utilized, and whether the correct legal conclusion was reached on that issue.

The determination was simply made on appeal that the Trial Court must have considered the prior art as a whole. That determination was apparently based on the detailed findings which were made as to each separate prior art reference and on the reference in the opinion of the Trial Court to the "prior art references either alone or in combination."[12]

However, one must look at the analysis of the prior art actually undertaken by the District Court, as reflected in its specific findings, and not at the conclusionary statements it made. Such an evaluation of the record below compels the conclusion that the District Court's findings were not "sufficiently comprehensive" so as to comply with Rule 52(a).

It is submitted that the findings by the District Court cannot reasonably be construed to be "sufficiently comprehensive" when they do not include: (a) any recognition that

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[12]*See* FN. 7 of the Court of Appeals' decision, *Medtronic*, 789 F.2d at 906, 229 USPQ at 667 (A-8).

the change of material of the tines from metal to silicone rubber was the only difference over the prior art; and (b) any discussion and analysis of whether certain combinations of the prior art reasonably suggested the use of silicone rubber as a pliant material for the previously known metal tines. The Court of Appeals compounded the error of omission by the District Court in failing to articulate and address those particular factual issues.

It was incumbent upon the Court of Appeals to at least state and consider the legal standard of obviousness as it relates to a mere change of material. In failing to do so the Court of Appeals has approved a standard for obviousness which is in direct conflict with the long-standing mandate of this Court originally iterated in *Hotchkiss v. Greenwood, supra,* and reaffirmed in *Graham, supra.*

This case thus presents to the Court for timely review the question of whether the Court of Appeals for the Federal Circuit may rely entirely upon the "clearly erroneous" standard applicable to factual findings, in reviewing lower court rulings on patent validity, without any consideration of whether the correct legal standards have been applied to the ultimate legal question. The Court of Appeals has not carried out the directive of this Court in *Dennison Manufacturing Company v. Panduit Corporation,* 106 S.Ct. 1578 (1986), requiring that the Federal Circuit provide its informed opinion on the complex issue of the degree to which the obviousness determination is one of fact. The decisions of this Court, reflecting a thorough analysis of the pertinent prior art, and the effect of the combined teachings of the prior art, under the applicable legal standards for patentability, strongly indicate that the Federal Circuit has not conducted the required scope of legal review.

CONCLUSION

There are compelling public policy reasons for granting this petition. In the instant case, as well as in the recent decision by the Court of Appeals for the Federal Circuit in *Polaroid Corporation v. Eastman Kodak Company*, 789 F.2d 1556, 229 USPQ 561 (1986), the Court of Appeals has so narrowly construed and applied the obviousness standard of 35 U.S.C. §103 and *Graham* as to virtually meld §103 into the novelty requirement for patentability of 35 U.S.C. §102. The result has been to sustain patentability where bare novelty is shown, without truly appraising obviousness from the proper standpoint of the combined teachings of two or more prior art references. In the instant case, that erroneous approach has resulted in sustaining a patent claim wherein the only difference over the prior art is in a change of material, with the substituted material being used for its previously known properties.

The Court of Appeals is thus now applying a level of innovation which falls far short of the standards established by this Court in *Hotchkiss v. Greenwood* and *Graham v. John Deere, supra.* This Court rejected the prior attempts to lower the standard for patentability in *Graham, supra,* 383 U.S. at 16, 148 USPQ at 466. The time is ripe and the need exists to do so again in order to reaffirm the proper standard for patentability.

Upon the record below, and for all the reasons set forth herein, a writ of certiorari should issue to review the judgment of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

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Counsel for Petitioner

Date: August 29, 1986

APPENDIX

APPENDIX

United States Court of Appeals for the Federal Circuit

Appeal No. 85-2645

MEDTRONIC, INC. AND MEDTRONIC PUERTO RICO, INC.,

Appellees,

vs.

DAIG CORPORATION,

Appellant.

DECIDED: April 30, 1986

Before BISSELL and ARCHER, Circuit Judges, RE Judge.*

BISSELL, Circuit Judge.

Daig Corporation (Daig) appeals from a judgment of the United States District Court for the District of Minnesota,[1] which found U.S. Patent No. 3,902,501 ('501) not proved invalid under 35 U.S.C. § 103 and infringed in a patent infringement action instituted by the assignee of the '501 patent, Medtronic, Inc. and its wholly-owned subsidiary, Medtronic Puerto Rico, Inc. (collectively called Medtronic). We affirm.

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*The Honorable Edward D. Re, Chief Judge, United States Court of International Trade, sitting by designation.

[1]Reported at 611 F.Supp. 1498, 227 USPQ 509 (D. Minn. 1985).

BACKGROUND

A. The Invention

A pacemaker is a device comprised of a pulse generator, a lead and a power source which is used to provide electrical stimulation to the heart in order to restore an acceptable heart rate in a patient whose rate is too low or erratic.

The two major types of pacemaker leads are myocardial leads and endocardial (or transvenous) leads. Myocardial pacemaker leads are either sutured or screwed into the tissue of the outside of the heart. The surgery necessary for myocardial lead fixation is disadvantageous because of the attendant trauma to the patient, the risks associated with major surgery, and the extended recuperation time. Endocardial leads were developed to alleviate the problems that accompany myocardial lead implantation.

An endocardial lead is inserted inside the heart through a vein. This requires a minor surgical procedure under local anesthesia, requiring a small incision in the vein through which a lead is passed to the desired location in the heart.

The invention of the '501 patent is directed to an endocardial pacemaker lead structure for transvenous implantation having a pacing electrode at its distal tip.[2] This endo-

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[2]Claim 1 of the '501 patent is:

1. In an endocardial lead of the type having an electrical conductor encased in a material which is generally inert to body fluids, the conductor terminating at an exposed electrically conductive electrode tip, the improvement which comprises:

nonconducting tine means extending from said encasing material and away from said tip from a location adjacent said tip for cooperating with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said encasing material and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.

cardial electrode, or tined lead, provides a means of passively fixing a medical electrode to heart tissue, particularly the trabeculae[3] of the ventricles[4] and the right atrial appendage.[5] The patented structure is a lead having a plurality of pliant, nonconducting tines which extend away from an exposed metal electrode tip and cooperate within the heart to hold the exposed electrode tip against the heart wall. This provides a suitable electrical relationship for transmitting pulses from a pacemaker pulse generator to the heart to properly time, or pace, the patient's heart beats. The tines provide this fixation without damaging or penetrating the heart tissue.

B. Proceedings and the District Court Opinion

Medtronic charged Daig with infringement of claim 1 of the '501 patent and U.S. Patent No. 3,737,579. Daig answered denying infringement and counterclaimed for a declaration of invalidity, and asserted antitrust violations. Daig later charged Medtronic with infringement of U.S. Patent 4,236,529 assigned to it. Medtronic defended by asserting patent invalidity and sought a declaratory judgment to that effect. The two actions were consolidated for trial. The trial judge ordered the trial trifurcated with the issues of patent validity and infringement to be tried first, the issues of damages relating to patent infringement to be tried second, and the issues of liability and damages relating to the antitrust unfair competition claims to be tried to a jury

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[3]Trabeculae are lattice-like structures or small bundles of muscle fibers in the ventricular apex or the right atrial appendage.

[4]The ventricles are the lower chambers of the heart which receive blood from a corresponding atrium (the upper chamber of the heart) and from which blood is forced into the arteries.

[5]The right atrial appendage is the ear- or auricle-like pouch of the right atrium.

last. When the trial commenced the court heard and received evidence with respect to claim 1 of the '501 patent only. The remaining issues were severed for a later, separate trial.

After a bench trial, the trial judge prepared a 107 page discussion of findings of fact and conclusions of law and adjudged the '501 not proved invalid and the accused devices used by Daig infringing claim 1 of the '501 patent.

ISSUE

Whether the trial judge erred in finding that claim 1 of the '501 patent was not obvious in view of the prior art.

OPINION

Daig presented this court with the same analysis of the prior art and testimony that was presented to the trial judge. It is not the role of this court to review *de novo* proceedings of a district court. Daig bears the burden of showing that the trial judge, in deciding the question of obviousness, committed reversible legal error, or that its probative findings underlying the legal conclusion were clearly erroneous in light of the record made at trial. *Carl Schenck, A.G. v. Norton Corp.*, 713 F.2d 782, 785, 218 USPQ 698, 700 (Fed. Cir. 1983); *see also, Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1555, 225 USPQ 26, 30 (Fed. Cir. 1985); *Atlas Powder Co. v. E.I. DuPont DeNemours & Co.*, 750 F.2d 1569, 1573, 224 USPQ 409, 411 (Fed. Cir. 1984). The "clearly erroneous" standard is satisfied when this court is left with the firm conviction that error has been committed. *See, e.g., Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983), *cert. denied*, 105 S.Ct. 127 (1984).

Daig argues that the trial judge erred in that he misunderstood the problem that the '501 invention overcame, misinterpreted the teachings and disclosures of the prior art, failed to understand the differences between certain prior art and the claimed invention and failed to consider the prior art as a whole in determining obviousness. Daig further argued that the record evidence does not establish commercial success attributable to the claimed tined lead.

OBVIOUSNESS

In assessing nonobviousness the following factual inquiries must be made: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of secondary considerations such a longfelt need, unexpected results, or commercial success. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); *see, e.g., Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575, 222 USPQ 744, 746 (Fed. Cir. 1984), *cert. denied*, 105 S.Ct. 2138 (1985).

The trial judge, Judge Larson, recognized the requisite *Graham* inquiries. He properly stated that prior art references "include pacemaker leads and catheter-like devices in general." A person of ordinary skill in this art in 1972 was determined to "have had a master's degree in electrical or mechanical engineering coupled with a basic knowledge of the physiology and anatomy of the heart and vascular system." Judge Larson proceeded to articulate a detailed analysis of the prior art cited to the U.S. Patent and Trademark Office and the additional references that were intro-

duced at trial, with each reference reviewed for what it taught and disclosed.[6]

No contest is had with the scope of the prior art or the level of ordinary skill in the art determinations. Instead, Daig's challenge with the trial's outcome begins with the premise that the problem solved by the '501 invention was incorrectly identified as the:

> development of an endocardial pacemaker lead with a means of passive fixation to reduce the incidence of lead dislodgement in the ventricles and right atrial appendage and to lessen the risk of tissue penetration or damage in the veins and heart chambers.

Nevertheless, Daig offers no alternative articulation of the problem and merely urges this court to find error in "undue emphasis" being placed on the lead dislodgement aspect of the problem. Daig continues by asserting that errors occurred in the discussion of the Schaldach article and the Rasor patent and that by analyzing the prior art references

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[6]A. The prior art cited to the PTO and principally relied on at trial included the following:

M. Schaldach, *New Pacemaker Electrodes*, 17 American Society for Artificial Internal Organs 29 (1971);

W. Portsmann, J. Witte, *et al., P Wave Synchronous Pacing Using Anchored Atrial Electrode Implanted Without Thoracotomy*, 30 The American Journal of Cardiology 74 (July 1972);

United States Patent No. 3,835,864 (Rasor);

United States Patent No. 3,719,190;

United States Patent No. 3,717,151;

United States Patent No. 3,516,410;

B. Prior art not cited to the PTO but considered at trial include:

German Patent No. 2,053,919

J. Spickler, N. Rasor, *et al., Totally Self-Contained Intracardiac Pacemaker*, 3 Journal of Electrocardiology 325 (1970);

United States Patent No. 3,492,996;

United States Patent No. 3,635,223;

Vitatron article, *Pacemaker Electrode*, 4 Bio-Medical Engineering 383 (1969);

Medtronic Endocardial leads Models 6901 and 6907.

individually, the trial court failed to consider the references as a whole. However, the alleged errors in the trial judge's understanding of the Schaldach article and Rasor patent amount to nothing more than argument. Judge Larson's interpretation of the references is amply supported by the record; it is not clearly erroneous.

We now turn our attention to the trial judge's discussion of the prior art teachings "as a whole." Under Rule 52(a) of the Federal Rules of Civil Procedure, in a non-jury trial, "the court shall find the facts specially and state separately its conclusions of law thereon . . . ." This court has recognized that failure to make specific factual findings is an abuse of discretion. *See e.g., Seattle Box Co., Inc. v. Industrial Crating & Packing*, 756 F.2d 1574, 1578, 225 USPQ 357, 360 (Fed. Cir. 1985) (it was error for the court to limit its statements on the equitable components of intervening rights to a mere ultimate conclusion, without any explanation of the particular factors and facts it considered); *Jones v. Hardy*, 727 F.2d 1524, 1529, 220 USPQ 1021, 1025 (Fed. Cir. 1984) (failure to make specific *Graham* findings constituted error). Such a failure has not occurred in this case.

While Rule 52(a) does require specific fact findings to be stated, the rule is not so severe as to require the trial judge to articulate every imaginable permutation and combination of prior art teachings. "The ultimate test of the adequacy of findings is whether they are sufficiently comprehensive and pertinent to the issue to form a basis for the decision (and whether they are supported by the evidence)." *Loctite Corporation v. Ultraseal Ltd.*, 781 F.2d 862, 872, 228 USPQ 90, 98 (Fed. Cir. 1985). While a complete discussion of all possible permutations and combinations of the

prior art would remove all doubt about whether the trial court properly reviewed the prior art for its total teachings we are convinced by the "express[ed] and necessarily implied findings" that Judge Larson properly viewed the prior art as a whole. *Id.; see also, Jones v Hardy*, 727 F.2d 1524, 1531, 220 USPQ 1021, 1027 (Fed. Cir. 1984) ("An appellate court's function is to review judgments, not opinions"); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 862, 226 USPQ 402, 408 (Fed. Cir. 1985) ("This court passes on judgments not opinions"). We presume that a fact finder reviews all the evidence presented unless he explicitly expresses otherwise.[7]

After conducting a thorough analysis of the prior art, the trial judge continued the *Graham* analysis by considering evidence of secondary considerations: commercial success, long-felt need in the medical community, contemporaneous invention, and other attempts to solve the problem of endocardial lead dislodgement. Daig sought to rebut Medtronic's commercial success claim by introducing evidence that no nexus existed between claimed commercial success and the tines of the '501 leads. The evidence and arguments regarding Medtronic's commercial success were evaluated as follows:

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[7]We are convinced that Judge Larson considered the prior art references for their combined teachings in arriving at the legal conclusion of nonobviousness as is indicated by his statement:

> The Court has attempted diligently to make the basic factual inquiries, under §103, as *Graham* requires, and to examine the results of those inquiries. The Court has also examined the evidence of secondary considerations. Upon full consideration *of all the evidence*, the Court finds that the invention claimed in the '501 patent would not have been obvious to a person having ordinary skill in the art at the time the invention was made. None of the prior art references, *either alone or in combination*, would have taught, disclosed, or suggested to a person of ordinary skill in the art the use of soft, pliant, nonconductive tines as a means of passive fixation for cooperating with heart tissue to hold the lead tip in position without penetrating the heart tissue. (Emphasis added.)

Medtronic, 611 F.Supp. at 1534, 277 USPQ at 535.

The Court has considered the evidence with respect to commercial success, and although the Court is not prepared to accept Medtronic's conclusion that its tined leads enjoyed tremendous commercial success, the Court is similarly not prepared to accept Daig's . . conclusion that the Medtronic tined leads enjoyed absolutely no commercial success. The Court, however, is satisfied that the Medtronic tined leads have enjoyed sufficient commercial success to suggest the nonobviousness of the tined endocardial lead disclosed in the '501 patent. In so concluding, the Court is not unaware of Daig's . . . concern that Medtronic tined leads should not be viewed as generic devices with tines, but rather individual devices with varied features and improvements other than tines. The Court is also not unaware of the possible influence that some of these varied features and iuprovements, such as a Multi-Filar coil and a ring tip electrode, may have had on tined lead sales . . . .

. . . .

In reaching the conclusion that the Medtronic tined lead has enjoyed some commercial success, the Court is not unmindful of Dr. Plotkin's conclusion to the contrary. Dr. Plotkin was an amply qualified and credible expert microeconomist, and his conclusion with respect to the commercial success of the tined leads was rooted deeply in economic theory and the capital market standard. His reliance on economic theory, however, perhaps so skewed his reasoning as to limit its applicability in terms of commercial success for purposes of this patent action. Dr. Plotkin defined commercial success for the tined lead, which he considered

a product innovation, to be an aggressive growth in market share. He could find no commercial success for Medtronic tined leads because the tined leads showed no aggressive growth in market share, and, in fact, the tined leads appeared to cannibalize Medtronic's existing endocardial lead market. Dr. Plotkin's definition and analysis of commercial success focused clearly, if not exclusively, on the economic effect of the product innovation, the tined lead, on the product innovator, Medtronic. Dr. Plotkin's definition and analysis of commercial success did not look to the effect, of any kind, of the product innovation on the industry as a whole. Such a definition and analysis could lead to the conclusion that a product innovation *per se* was not a commercial success, but the same product innovation nonetheless had a profound influence on the industry and market. That conclusion may well be what Dr. Plotkin offered the Court. In a pure economic analysis, using, as Dr. Plotkin described it, the "tough" capital market standard, the Medtronic tined lead was probably not commercially successful. In a rather pragmatic analysis, however, looking to a pacing industry which now intensively markets tined leads, and to a medical community which now regards tined leads as leads of choice, the Medtronic tined lead was commercially successful. The Court is satisfied that Medtronic has shown that its tined leads, which embody the advantages inherent in the endocardial lead disclosed in the '501 patent, have enjoyed sufficient commercial success to suggest nonobviousness (footnote omitted).

Medtronic, 611 F.Supp. at 1531-32, 227 USPQ at 533-34.

In conclusion, Daig has merely argued to this court the same arguments made at trial concerning the obviousness/nonobviousness of the '501 patent. The trial judge articulated a careful analysis and we are not persuaded that reversible legal error has occurred in the determination that the invention of the '501 would not have been obvious; nor are we convinced that the trial judge's findings underlying that determination are clearly erroneous.

As a final effort to prove obviousness of the '501 invention, Daig urges this court to adopt the conclusion of a German tribunal holding the '501 German counterpart patent obvious This argument is specious. The patent laws of the United States are the laws governing a determination of obviousness/nonobviousness of a United States patent in a federal court. *See In re Dulberg*, 472 F.2d 1394, 176 USPQ 525 (CCPA 1973); *In re Larson*, 292 F.2d 531, 130 USPQ 209 (CCPA 1961).

For the foregoing reasons, we affirm the judgment that Daig failed to prove the '501 patent invalid.

AFFIRMED

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
FOURTH DIVISION

Civil File No. 4-79-256
Civil File No. 3-83-251

Medtronic, Inc. and Medtronic Puerto Rico, Inc.,
Plaintiffs

vs.

Daig Corporation,
Defendant.

and

Pacesetter Systems, Inc.,
Plaintiff,

vs.

Medtronic, Inc. and Medtronic Puerto Rico, Inc.,
Defendants.

MEMORANDUM ORDER

Robert T. Edell, Albert L. Underhill, and Joseph F. Breimayer appeared on behalf of Medtronic, Inc. and Medtronic Puerto Rico, Inc.

Malcolm L. Moore and Daniel J. Starks appeared on behalf of Daig Corporation.

Donald L. Cox, Mary Janice Lintner, and Robert R. Meads appeared on behalf of Pacesetter Systems, Inc.

INTRODUCTION

The matter before the Court began in 1979 as a relatively straightforward patent infringement action. In the six

years which followed, however, the matter proliferated such that almost every federal district judge in Minnesota was involved in this matter at one time or another; the matter spawned related actions in Texas and Florida which now have been stayed pending this decision or transferred to Minnesota for decision; and the matter attracted the keen attention and required the significant investment of time, money, and effort of a number of corporations in the competitive field of pacemaker pulse generators and pacemaker leads. Now, in 1985, the Court, having given its careful consideration to the matter, hopes to render a decision which will show the matter to be the straightforward patent infringement action it is, and signal the beginning of the end for this unnecessarily protracted and unduly complicated litigation.

Medtronic, Inc. and its wholly owned subsidiary Medtronic Puerto Rico, Inc. (Medtronic) commenced this patent infringement action against Daig Corporation (Daig) on May 29, 1979 in the United States District Court for the District of Minnesota. The action was assigned to Judge Harry H. MacLaughlin under Civil No. 4-79-256. Medtronic alleged that Daig had infringed the claims of its assigned United States Patent No. 3,902,501 ('501 patent) and No. 3,737,579 ('579 patent). Medtronic requested that Daig be enjoined from infringing the '501 and '579 patents and account for and pay damages which resulted from Daig's infringement. Medtronic also asserted that Daig's infringement was willful, deliberate, and intentional and requested that the damages be trebled. On July 18, 1979, Daig filed its Answer and Counterclaim and, on February 3, 1981, Daig, with leave of court, filed its Amended Answer and Counterclaim. In its Amended Answer and Coun-

terclaim, Daig asserted the affirmative defenses that the '501 and '579 patents were invalid under 35 U.S.C. §§ 102, 103, and 112, that Medtronic was estopped by its actions in the negotiations and proceedings involving the '501 and '579 patent applications before the United States Patent and Trademark Office (PTO), that Medtronic had misused the '501 and '579 patents in this infringement action, and that, with respect to the '501 patent, Medtronic had displayed a lack of candor with the PTO having failed to disclose the wedge tip pacemaker leads which Medtronic marketed commercially as Models Nos. 6901 and 6907. Daig sought declaratory judgment that the '501 and '579 patents were invalid. Daig also alleged that Medtronic's conduct violated federal antitrust law, 15 U.S.C. §§ 1 and 2, state antitrust law, Minn. Stat. §§ 325.8011 - 325.8028 (renumbered Minn. Stat. §§ 325D.49 - 325D.66), and constituted unfair means and methods of competition. Daig requested that Medtronic's conduct be enjoined and that Daig be awarded treble damages.

On December 16, 1980, Daig commenced a separate patent infringement action against Medtronic in the United States District Court for the District of Minnesota. The action was assigned to Judge Diana E. Murphy under Civil No. 4-80-611. Daig alleged that Medtronic had infringed its assigned United States Patent No. 4,236,529 ('529 patent) and sought injunctive relief and money damages as determined by an accounting. Medtronic filed its Answer and Counterclaim on January 12, 1981 in which it asserted the affirmative defenses of invalidity under 35 U.S.C. §§ 102, 103, and 112, file wrapper estoppel, and fraud in the procurement of the '529 patent, and sought declaratory judgment that the '529 patent was invalid. On January 13,

1981, the patent infringement actions, Civil Nos. 4-79-256 and 4-80-611, were consolidated for all pretrial purposes and trial before Judge MacLaughlin. These actions were subsequently reassigned to Judge Paul A. Magnuson upon his appointment to the federal bench on November 16, 1981.

On June 10, 1981, a petition in involuntary bankruptcy for a liquidation proceeding under Chapter 7 of the Bankruptcy Code was filed against Daig. Daig promptly converted the proceeding to a reorganization proceeding under Chapter 11 on June 16, 1981. The infringement actions, Civil Nos. 4-79-256 and 4-80-611, were stayed pursuant to the automatic stay provisions of the Bankruptcy Code. On January 22, 1982, Medtronic commenced an adversary proceeding in the United States Bankruptcy Court for the District of Minnesota in which Medtronic sought modification of the automatic stay. The matter came on for trial before the Bankruptcy Court on March 9, 1982 and the Bankruptcy Court modified the automatic stay on April 15, 1982. The Bankruptcy Court permitted Medtronic to proceed against Daig in Civil No. 4-79-256 and to defend in Civil No. 4-80-611 to obtain an infringement determination and injunctive relief, if appropriate.

Medtronic then filed a Motion for Expedited Trial Date which was denied on August 12, 1982. On October 13, 1982, Medtronic followed with a Motion for Preliminary Injunction seeking to enjoin Daig from manufacturing, using, or selling any pacemaker leads within the terms of the claims of the '501 patent. Daig responded with its Motion to Stay on November 17, 1982 asking the Court to stay the litigation between Medtronic and Daig with respect to the '501 patent pending a determination of the

validity of that patent in another infringement action, *Medtronic, Inc. and Medtronic Puerto Rico, Inc. v. Intermedics, Inc.*, Civil No. G-80-295, which was then pending in the United States District Court for the Southern District of Texas. Daig, as a condition to a stay of the Medtronic litigation in Minnesota, agreed to be bound by the determination of the Intermedics litigation in Texas as to the validity of the '501 patent. On November 24, 1982, the Court denied Daig's Motion to Stay and scheduled Medtronic's Motion for Preliminary Injunction for January 10, 1983. Following a nine day hearing, the Court, on May 20, 1983, ordered Daig not to make, use, or sell silicone or other tined leads embodying the elements of Claim 1 of the '501 patent during the pendency of this action. On August 29, 1984, the Court, having found that the equities and the improved financial condition of Daig warranted lifting the injunction, vacated the preliminary injunction conditioned upon the ability and willingness of Daig to comply with an escrowed royalty arrangement with Medtronic.

On August 21, 1981, Pacesetter Systems, Inc (Pacesetter) commenced a declaratory judgment action against Medtronic in the United States District Court for the Central District of California. Pacesetter sought to have the '501 patent declared invalid and not infringed by Pacesetter. The action was transferred to the United States District Court for the District of Minnesota on February 11 1983 where it was assigned to Judge Donald D. Alsop under Civil No. 3-83-251. Medtronic filed its Answer and Counterclaim on March 28, 1983 and asserted that Pacesetter had willfully, deliberately, and wantonly infringed the '501 patent. Medtronic sought injunctive relief and treble money damages. This action, having been found to

be a companion case to Civil Nos. 4-79-256 and 4-80-611, was reassigned to Judge Magnuson on June 13, 1983.

Pacesetter, like Daig, filed a Motion to Stay on May 27, 1983 asking the Court to stay discovery and trial pending a final determination of the validity of the '501 patent in *Medtronic, Inc. and Medtronic Puerto Rico, Inc. v. Intermedics, Inc.*, Civil No. G-80-295, which was pending in the United States District Court for the Southern District of Texas. As a condition to a stay of the proceedings in Minnesota, Pacesetter agreed to be bound by the determination of the validity of the '501 patent in the Intermedics litigation in Texas. On August 5, 1983, Pacesetter, following a determination in the Intermedics litigation that the '501 patent was valid and infringed, withdrew its Motion to Stay. Medtronic then brought a Motion for Preliminary Injunction which was denied on August 30, 1983. Medtronic and Pacesetter later brought Cross-Motions for Summary Judgment which were denied on April 18, 1984.

The Court, having determined that the issues of patent validity and infringement in Civil No. 3-83-251 involved common questions of law and fact with the issues of patent validity and infringement in consolidated Civil Nos. 4-79-256 and 4-80-611, consolidated Civil Nos. 3-83-251, 4-79-256, and 4-80-611 for trial. The Court then ordered the trial trifurcated with the issues of patent validity and infringement to be tried to the Court first, the issues of damages relating to patent infringement to be tried to the Court next, and the issues of liability and damages relating to the antitrust and unfair competition claims to be tried to a jury last.

Trial commenced before Judge Earl R. Larson on February 14, 1985 and continued, with only the interruption of a classic Minnesota blizzard, until its conclusion on

March 20, 1985. The Court heard and received evidence with respect to Claim 1 of the '501 patent only. Essentially, the consolidated actions before the Court were Civil Nos. 4-79-256 and 3-83-251. Remaining issues await trial another day. This Memorandum Order comprises the findings of fact and conclusions of law of the Court pursuant to Rule 52(a) of the Federal Rules of Civil Procedure. This Order is the product of careful and detailed attention to the witnesses and evidence presented and the numerous legal issues raised. Where conflicts existed in the testimony, and conflicts there were, facts have been found on the basis of close observation of the appearance, conduct, and demeanor of the witnesses, and scrutiny of contemporaneous documentation or exhibits, if available.

PATENT IN SUIT

At issue in this trial is the validity of United States Patent No. 3,902,501 (PX 1)[1] entitled "Endocardial Electrode." Paul Citron and Eugene A. Dickhudt are the inventors of this endocardial electrode and they assigned their interest in it to Medtronic. Their patent application was filed on June 21, 1973 and the '501 patent was issued on September 2, 1975. This endocardial electrode, or tined lead, provided a unique means of passively fixing a medical electrode to heart tissue, particularly the trabeculae[2] of the ventricles[3] and the right atrial appendage.[4] The new

[1]For convenient reference, the Court will use the following abbreviations:
PX - Medtronic Exhibit
DX - Daig Exhibit
PSX - Pacesetter Exhibit

[2]Trabeculate are lattice-like structures of small bundles of muscle fibers in the ventricular apex or the right atrial appendage.

[3]The ventricles are the lower chambers of the heart which receive blood from a corresponding atrium (the upper chamber of the heart) and from which blood is forced into the arteries.

[4]The right atrial appendage is the ear- or auricle-like pouch of the right atrium.

lead employed a plurality of pliant nonconducting tine means adjacent to the electrode tip to cooperate with the heart tissue. The pliant nonconducting tines offered a more effective way of passively fixing the lead to heart tissue until natural fixation or fibrosis[5] could occur and without damaging the affected venal or heart tissue.[6] The '501 patent specifically claimed:

> 1. In an endocardial lead of the type having an electrical conductor encased in a material which is generally inert to body fluids, the conductor terminating at an exposed electrically conductive electrode tip, the improvement which comprises:
>
> > nonconducting tine means extending from said encasing material and away from said tip from a location adjacent said tip for cooperating with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said encasing material and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.

(PX 1, column 6, lines 50-66).

Claim 1 is the only claim of the '501 patent in dispute here.

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[5]Fibrosis is the process by which scar tissue forms at the site of an injury to a muscle or organ of the body.

[6]The Court uses the terms passive fixation and active fixation in contrast to each other. Passive fixation refers to the non-traumatic placement of a lead at a desired location in the heart, often the trabeculae. Active fixation, on the other hand, refers to the traumatic placement of a lead at a desired location, often using a grasping, biting, pinching, piercing, penetrating, impaling, or screwing mechanism.

Paul Citron came to Medtronic in February 1972 with a bachelor's degree and a master's degree in electrical engineering to develop an atrial pacing system. With essentially no experience in pacing, but with the background of a self-described hybrid masters program involving medical and veterinary courses in anatomy and physiology, Citron pondered his task. He studied the anatomy of the human heart, the literature involving atrial pacing, and the available technology. The study of his task made clear to him that the problem then confronting atrial pacing was twofold. First, the pacemaker or pulse generator, the device which both senses the rate and amplitude of electrical impulses of the heart and stimulates the heart with a self-generated electrical impulse to restore an acceptable heart rate, was itself a problem involving the capability of the pulse generator to sense accurately the electrical activity of the heart and to stimulate properly the heart as necessary. Second, the lead system, the means by which the pulse generator senses the electrical impulses of the heart and transmits stimulating electrical impulses to the desired location in the heart, was a problem because no reliable atrial pacing lead system existed. The absence of a reliable atrial pacing lead system, in Citron's opinion, was of paramount concern and on that problem he focused his attention and energy.

While no reliable atrial pacing system existed in 1972, a variety of epicardial or myocardial leads and endocardial or transvenous leads, commonly used in ventricalar pacing, had been used in atrial pacing. Epicardial leads, which were actually attached to the outer surface or the epicardium[7] or myocardium[8] of the heart, including a screw-on lead (PX

[7]The epicardium is the thin fibrous layer covering the outside of the heart.
[8]The myocardium is the middle muscular layer of the heart wall.

29) and a suture-on lead (PX 28). A screw-on lead was actively fixed within the myocardium in a corkscrew-like fashion. A suture-on lead was actively fixed to the myocardium with silk sutures. The fixation of epicardial leads required one of three significant surgical procedures, including a major thoracotomy,[9] a minor thoractomy,[10] or a subxiphoid approach.[11] The major surgery necessary for the fixation of epicardial leads was a major disadvantage of epicardial leads because of the attendant trauma and risks of major surgery and the extended recuperation time.

Endocardial or transvenous leads, which were positioned within the heart by insertion through a vein, included a straight-shank lead, a wedge tip or flange lead (PX 30), and a helical lead. A straight-shank lead and a flange lead were inserted transvenously into the heart and passively fixed within the trabeculae of the right atrial appendage or ventricalar apex where it was hoped the lead tip woud remain in contract with the endocardium.[12] A helical lead was also inserted transvenously into the heart, but it involved a helically shaped barb or hook mechanism which was actively fixed to the endocardium by rotating the device. The placement or positioning of endocardial leads required a minor surgical procedure under local anesthesia which involved cannulating a vein and using a catheter through

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[9]A major thoracotomy, or a sternal or midline thoracotomy, involves a 10-12 inch incision in the sternum with the sternum then being spread—literally cracking open the rib cage—to allow access to the heart.

[10]A minor thoracotomy, or a lateral thoracotomy, involves a 2-3 inch incision in the left lateral, fifth inner rib space to allow access to the heart.

[11]A subxiphoid approach, or tunnelling technique, involves an incision over the xiphoid process, which is a small cartilaginous triangular bone of the sternum, the removal of that bone, and an incision in the diaphragm to allow access to the inferior surface of the heart.

[12]The endocardium is the thin inner lining of the heart which covers the myocardium.

which the lead would be passed to the desired location in the heart. The relatively non-traumatic procedure and quick recovery time were significant advantages of endocardial leads. Endocardial leads, however, also had disadvantages involving acute dislodgement, where the electrode tip of the lead lost contact with the endocardium or wall of the heart, and perforation, where the electrode tip punctured the endocardium.

Citron, along with Eugene Dickhudt, a mechanical technician for Medtronic, began to design atrial lead systems. As Citron's laboratory notebook (PX 42) evidences, Citron and Dickhudt toyed with a number of lead designs in early 1972. Some of these lead designs included: the earthworm endocardial lead (PX 42, pp. 1-2) which was intended to allow both atrial and ventricalar pacing through the same lead; the cyanoacrylate myocardial lead (PX 42, pp. 2 and 12-16) which envisioned literally gluing the lead to the myocardium; the barbed myocardial lead (PX 42, pp. 17 and 19) which used conductive fishhooks or barbs to fix the lead to the myocardium; the vacu-tach lead (PX 42, p. 17) which was intended to fix the fishhook lead to the myocardium of the atrium with a vacuum pump; the vena iava atrial lead (PX 42, pp. 20 and 24-25) which was a flat myocardial lead to be wrapped around the superior vena cava and secured with glue or sutures; and the double twang lead or endocardial s-a node electrode (PX 42, p. 26) which, upon positioning in the atrium, would bifurcate into two smaller J-shaped leads with electrode tips. On July 7, 1972, Citron entered in his lab notebook a sketch of "a new concept for an atrial endocardial lead" which he called the grapnel (PX 42, p. 50). Citron envisioned a flexible endocardial lead body with a skirt of a number of pliant

silicone rubber tines which could be positioned in the right atrial appendage, and possibly the ventricles. Citron intended the tined skirt of the lead to extend approximately 45° from the axis of the lead body and to be positioned with a hold-down mechanism or with the tines free-standing. Dickhudt built the first prototype of the grapnel lead and Citron entered a picture of it in his lab notebook on July 13, 1972 (PX 42, p. 51). The grapnel would eventually come to be known as the tined endocardial lead which Claim 1 of the '501 patent embraces.

VALIDITY OF THE '501 PATENT

Presumption of Validity

In order to be patentable, an invention must satisfy three explicit statutory conditions: (1) utility (35 U.S.C. § 101); novelty (35 U.S.C. § 102); and (3) nonobviousness (35 U.S.C. § 103). *Graham v. John Deere Co.*, 383 U.S. 1, 12 (1966).[13] A patent once issued, however, is presumed valid and the burden of establishing that a patent is invalid rests on the party asserting such invalidity. 35 U.S.C. § 282. Section 282 "mandates not only a presumption shifting the burden of going forward in a purely procedural sense, but also places the burden of persuasion on the party who asserts that the patent is invalid." *Solder Removal Co. v. United States International Trade Commission*, 582 F.2d 628, 632 (C.C.P.A. 1978) (footnote omitted). That bur-

[13]Daig and Pacesetter do not seriously dispute the utility of the tined endocardial lead which Claim 1 of the '501 patent embraces, and the Court notes that the evidence supports such a finding of utility. Rather, Daig and Pacesetter challenge the novelty of the '501 patent under §§ 102(a), (b), and (g), and the nonobviousness of the '501 patent under § 103. Additionally, Daig and Pacesetter challenge the validity of the '501 patent under §112.

den, which always remains with the party asserting invalidity, is to persuade the Court of invalidity by clear and convincing evidence. *American Hoist & Derrick Co. v. Sowa & Sons,* 725 F.2d 1350, 1360 (Fed. Cir.), *cert. denied,* 105 S.Ct. 95 (1984). The only question for the Court is whether that burden has been successfully carried. *Id.*

When the party asserting the invalidity of a patent relies only on the prior art which the PTO examiner considered, that party has the added burden of overcoming the deference due to the PTO. The PTO, through examiners of some expertise in scrutinizing and interpreting prior art references and familiarity with the level of skill in the art, is presumed to have properly performed its function of issuing only valid patents. The added burden on the challenger in this situation is to show that the PTO erred in granting the patent. *Id.* at 1359-60.

When the party asserting invalidity offers prior art or other evidence which the PTO examiner did not consider, the deference due the PTO is reduced or eliminated because the PTO has not applied its expertise to this art and the Court, consequently, is not faced with having to disagree with the PTO. *Id.* The introduction of prior art which the PTO examiner did not consider does not weaken or otherwise affect the presumption of validity. The burden of persuasion remains clear and convincing evidence. That burden, however, may be met more easily when the prior art which was not considered is more pertinent than the cited art. *Lindemann Mashchinenfabrik v. American Hoist and Derrick,* 730 F.2d 1452, 1459 (Fed. Cir. 1984). Whether the uncited art is more pertinent turns on its relationship to the claimed invention. Pertinence is the touchstone with respect to the uncited art. A presumption that the examiner

considered the uncited art because it is found in the classes and subclasses which the examiner searched is, therefore, unneecssary. To the extent that the examiner's consideration of uncited art is material, the challenger incurs the additional burden of showing that the uncited prior art was not considered. The challenger can meet this added burden by showing that the uncited art is more pertinent than the cited art. Conversely, the patenteee can thwart the challenger in this regard by showing that the pertinence of the uncited art is equal to or less than that of the cited art. *Id.* at 1460.

§ 102

Section 102 provides in relevant part that:

> A person shall be entitled to a patent unless—
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
>
> * * *
>
> (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive

and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 102.

A party asserting that a patent claim is anticipated under § 102 must establish that "each element of the claim in issue is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice." *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied,* 104 S.Ct. 1284 (1984). The anticipating reference need not "teach" what the patent in suit teaches. Rather, it is sufficient that the claim being challenged "read on" something disclosed in the reference, i.e., all limitations of the claim are found in the reference or are "fully met" by it. *Id.* at 772. The Court, in considering anticipation, must first identify the elements of the claim in issue, determine the meaning of those elements in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *Id.* at 771; *Lindemann Maschinenfabrik v. American Hoist and Derrick,* 730 F.2d 1452, 1458 (Fed. Cir. 1984).

When a party asserts that a prior use anticipates a patent claim under § 102(a) or (b), that party must also establish that such a use was of a complete invention, *i.e.*, conceived and reduced to practice, and public. *Coffin v. Ogden,* 85 U.S. (18 Wall.) 120, 124 (1873); *International Glass Company v. United States,* 408 F.2d 395, 402 (Ct. Cl. 1969). Reduction to practice requires that an invention be sufficiently tested to demonstrate that it will work for its intended purpose. *Kimberly-Clark Corp. v. Johnson & Johnson,* 745

F.2d 1437, 1444 (Fed. Cir. 1984) (citing *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 838 (Fed. Cir. 1984)). Reduction to practice does not require that the invention, when tested, be in a commercially satisfactory stage of development. *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 838 (Fed. Cir. 1984). To determine whether a public use has occurred requires consideration of all the circumstances surrounding the use. *TP Laboratories, Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 971-72 (Fed. Cir.) *cert. denied*, 105 S.Ct. 108 (1984). Circumstances surrounding the use to be considered include whether payment is made for the device, whether a user agreed to use secretly, whether records were kept of progress, whether persons other than the inventor conducted tests or experiments, how many tests or experiments were conducted, and how long the testing period was in relationship to tests of other similar devices. *Id.* at 972. That a non-secret use of the device was made or that the device was not hidden from view is not *ipso facto* public use. *Id.*

Where a party asserts that a prior invention anticipates a patent claim under § 102(g), that party must establish that such an invention is complete, *i.e.*, conceived and reduced to practice, and not abandoned, suppressed, or concealed. *Coffin v. Ogden*, 85 U.S. (18 Wall.) 120, 124 (1872); *International Glass Company v. United States*, 408 F.2d 395, 402 (Ct. Cl. 1969). If the invention is not complete or reduced to practice, whether it was abandoned, suppressed, or concealed matters not for the inventor has nothing to offer or disclose to the public. *Id.* If the invention is complete or reduced to practice, however, it may be deemed abandoned, suppressed, or concealed if, within a

reasonable time after completion, no steps, such as filing a patent application, describing the invention in a publicly disseminated document, or using the invention publicly, have been taken to make the invention publicly known. *International Glass Company v. United States,* 408 F.2d 395, 403 (Ct. Cl. 1969).

Claim 1 of the '501 patent may be stated in terms of its elements as follows:

> 1. In an *endocardial lead* of the type having an *electrical conductor encased in a material which is generally inert to body fluids,* the conductor terminating at an *exposed electrically conductive electrode tip,* the improvement which comprises:
> nonconducting tine means
> extending from said encasing material and away from said tip from a location adjacent said tip
> for cooperating with heart tissue, to hold the tip in position,
> said tine means forming a generally acute angle with said material
> and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained,
> but sufficiently pliant to prevent penetration of said heart tissue,
> said pliant material being generally inert to body fluids.

Claim 1 contemplates an improvement to an endocardial lead which increases the reliability of electrode securement and reduces the incidence of perforation. The improvement consists of the addition of a plurality of nonconductive tine

means to the endocardial lead. The tine means extend from the lead body or encasing material and away from the tip of the lead. The tine means are located adjacent or near the tip of the lead and form an acute angle, such as 45° with the lead body. The tine means are made entirely of a pliant material inert to body fluids, such as silicone rubber or polyurethane, which is sufficiently rigid to maintain the angle of the tine means when they are unrestrained, but sufficiently flexible to avoid penetration of heart tissue upon insertion and placement. The tine means are designed to hold the lead tip in electrical contact with heart tissue through cooperation with heart tissue, particularly trabeculae of the right atrial appendage or ventricles, until natural fixation or fibrosis has occurred (*See* PX 1, Figure 1). The elements of Claim 1 find support and correspondence in the specification and prosecution history of the '501 patent.

Pacesetter contends that the '501 patent was anticipated under § 102 in at least three ways: 1) anticipation by publication; (2) anticipation by prior use; and (3) anticipation by prior invention. Daig offers no serious argument for anticipation under § 102. According to Pacesetter, a barbed lead falling squarely within each element of Claim 1 of the '501 patent was disclosed in a 1969 printed publication, *Pacemaker Electrode,* 4 Bio-Medical Engineering 383 (August 1969) (PSX 10b). This reference is prior art for purposes of § 102 because it is undisputed that the reference was published before the invention of the tined lead (July 7, 1972) and more than one year before the application for the '501 patent (June 21, 1973). This reference, which was but a blurb relating to new products in medical instrumentation, is reprinted in its entirety as follows:

PACEMAKER ELECTRODE

Vitatron Medical N.V. of Holland has announced a new unipolar intracardiac catheter electrode, type MIP 135, for long term stimulation by implanted pacemakers. It can be used with all Vitatron pacemakers as well as with most other types of pacemaker including on-demand types.

The new electrode consists of a platinum-iridium electrode tip and a helically coiled lead of Elgiloy, insulated by a tube of silicone rubber. A stainless steel stylet can be placed in the lumen of the helical coil for the introduction of the catheter electrode.

The tip is fitted with a small barbed silicone ring to prevent dislocation in the critical postoperative period.

(PSX 10b, p. 383).

To Pacesetter, this Vitatron reference discloses each element of Claim 1 of the '501 patent (*See* PSX 8i).

This reference discusses an improvement to an endocardial electrode which is designed to reduce dislodgement in the critical postoperative period and which is embodied in the Vitatron MIP 135. The improvement consists of the electrode tip being fitted with "a small barbed silicone ring." For Pacesetter, the Vitatron improvement is clearly synonymous with the improvement of the '501 patent. For the Court, however, the Vitatron improvement, as both stated and pictured (*See* PSX 10b, pp. 382 and 383), is ambiguous. This ambiguity precludes the Vitatron reference from anticipating Claim 1 of the '501 patent because the Court cannot satisfactorily determine whether each element of Claim 1 is found in the reference.

While some elements of Claim 1 are found in the Vita-

tron reference, such as an endocardial lead (a unipolar intracardiac catheter electrode, type MIP 135), with an electrical conductor (a helically coiled lead of elgiloy), encased in a material inert to body fluids (insulated by a tube of silicone rubber), and an exposed electrically conductive electrode tip (a platinum-iridium electrode tip), not all elements of Claim 1 are clearly found in the reference, particularly nonconducting tine means extending away from the lead body at an acute angle for cooperating with heart tissue to hold the tip in position. Because each element of Claim 1 cannot be found in the Vitatron reference, the Vitatron reference does not anticipate Claim 1 of the '501 patent.

Pacesetter focuses on the phrase "a small barbed silicone ring" as the Vitatron embodiment of the Claim 1 concept. In this phrase, Pacesetter finds each element of Claim 1. But the phrase "a small barbed silicone ring" alone discloses simply three adjectives loosely modifying a solitary noun. Read literally, the phrase describes a ring which is small, which is barbed, and which is silicone. The elements of Claim 1 are not apparent in this phrase. Read in the light of hindsight, however, the phrase gains the allure of being a rather convenient and shorthand description of a tined endocardial lead such as that of Claim 1. This description, according to Pacesetter, must surely anticipate the tined endocardial lead as disclosed in Claim 1. Yet, it is hindsight, as Pacesetter's evidence on this point illustrates, which informs the phrase "a small barbed silicone ring" and allows one to "read on" the elements of Claim 1 in the Vitatron reference. Hindsight, however, has no place in considering anticipation and without it the Vitatron reference remains ambiguous and incapable of anticipating Claim 1.

Perhaps telling of the weakness of the Vitatron reference as an anticipating publication was Medtronic's introduction of clearer photographs of Vitatron leads which embodied "a small barbed silicone ring." Because Pacesetter's witness Dr. Tomlinson was unable to say whether the photograph of Vitatron MIP 135 in the Vitatron reference disclosed a tined endocardial lead (PSX 10b, p. 382), Medtronic sought to introduce a clearer picture as found in a Vitatron MIP 135 sales brochure (PX 208). Although Dr. Tomlinson found the photograph inadequate for purposes of determining whether the lead had tine means or similar projections, the Court finds the photograph sufficient to establish that the Vitatron MIP 135 did not have tine means as disclosed in Claim 1. The Court, in fact, finds the photograph sufficiently clear to establish that the Vitatron MIP 135 was a flange wedge tip lead. Medtronic also introduced, over Pacesetter's strenuous objection, other Vitatron sales brochures which used the phrase "a small barbed silicone ring" to describe a flange or wedge tip lead *(See, e.g.,* PX 207). The Court is of the opinion that the phrase "a small barbed silicone ring" as used in connection with Vitatron endocardial leads does not refer to the improvement disclosed in Claim 1 of the '501 patent. Rather, the phrase "a small barbed silicone ring" as used in the printed publications of 1969 referred to a common flange or wedge tip endocardial lead.

Pacesetter also contends that barbed leads fulfilling each element of Claim 1 of the '501 patent existed in August 1971 before the invention of the tined lead (July 7, 1972) and more than one year before the application for the '501 patent (June 21, 1973). According to Pacesetter, Dr. Schulman conceived the idea of a barbed pacemaker lead in

1970 and reduced the barbed lead to practice and publicly used it by August 1971. Pacesetter offered the testimony and related exhibits of Joseph Schulman, James Beazell, Gerald Adomian, Harry Fletcher, Leslie Lettau, Mary Craig, and Albert Rambo to show prior use and prior invention of a barbed or tined endocardial lead. This evidence, however, was largely without the support of contemporaneous and reliable notes, reports, photographs, or other documents, let alone the claimed barbed lead itself. Often the evidence was unclear, obscure, inaccurate, contradictory, inconsistent, and generally wanting of credibility. Nevertheless, Dr. Schulman and others at Pacesetter believe that they actively researched and experimented with the barbed lead through 1974. This prior invention and public use of a barbed lead, Pacesetter concludes, clearly anticipates Claim 1 of the '501 patent.

Because Pacesetter offered mainly the unsupported oral testimony of witnesses to show prior use and invention, the Court views such testimony with suspicion and subjects it to close scrutiny. *E.I. Du Pont de Nemours v. Berkley & Co., Inc.*, 620 F.2d 1247, 1261 (8th Cir. 1980). The Court considers the sufficiency of this testimony in the light of various factors which include: (1) the delay between the event and trial; (2) the interest of the witnesses; (3) contradiction or impeachment; (4) corroboration; (5) the witnessess' familiarity with details of the alleged prior structure; (6) the improbability of prior use considering state of the art; (7) the impact of the invention on the industry; and (8) the relationship between the witnesses and the alleged prior user. *Id.* at n. 20.[14]

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[14]That the unsupported oral testimony of Pacesetter's witnesses with respect to the anticipation of the '501 patent is "open to grave suspicion" derives from the observations of the Supreme Court in *The Barbed Wire Patent*, 143 U.S. 275 (1892).

Joseph Schulman went to work for Standard Scientific Systems, Inc., now Pacesetter Systems, Inc., in April 1969 after receiving his doctorate in biology from the University of California at Los Angeles (UCLA). With the financial backing of Al Mann, Schulman rented a small garage facility in Van Nuys, California for Standard Scientific, ordered materials, parts, and testing equipment, and set out to develop a commercially feasible rechargeable pacemaker or pulse generator. The rechargeable pacemaker, not the pacemaker lead, was the primary interest of Schulman and Pacesetter during Pacesetter's early years, including 1970-72. All research and experimental efforts were directed primarily to the rechargeable pacemaker.

> We have now to deal with certain unpatented devices, claimed to be complete anticipations of this patent, the existence and use of which are proven only by oral testimony. In view of the unsatisfactory character of such testimony, arising from the forgetfulness of witnesses, their liability to mistakes, their proneness to recollect things as the party calling them would have them recollect them, aside from the temptation to actual perjury, courts have not only imposed upon defendants the burden of proving such devices, but have required that the proof shall be clear, satisfactory and beyond a reasonable doubt. Witnesses whose memories are prodded by the eagerness of interested parties to elicit testimony favorable to themselves are not usually to be depended upon for accurate information. The very fact, which courts as well as the public have not failed to recognize, that almost every important patent, from the cotton gin of Whitney to the one under consideration, has been attacked by the testimony of witnesses who imagined they had made similar discoveries long before the patentee had claimed to have invented his device, has tended to throw a certain amount of discredit upon all that class of evidence, and to demand that it be subjected to the closest scrutiny. Indeed, the frequency with which testimony is tortured, or fabricated outright, to build up the defence of a prior use of the thing patented, goes far to justify the popular impression that the inventor may be treated as the lawful prey of the infringer.

Id. at 284-85.

These observations remain valid in principle today and are particularly appropriate in this case. While the Court intends in no way to require proof of prior use beyond a reasonable doubt, as was suggested in *The Barbed Wire Patent*, the Court will accept nothing less than proof of prior use by clear and convincing evidence. *See Trans-World Manufacturing Corp. v. Al Nyman & Sons, Inc.*, 750 F.2d 1552, 1559 (Fed. Cir. 1984) (citing *E.I. Du Pont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247, 1261 (8th Cir. 1980).

Schulman believes that he first saw an endocardial lead with silicone rubber tines or barbs when he made a prototype of such a lead in 1970. He described the barbs as being soft and flexible so that when the lead was inserted in the vein the barbs would fold down the lead body, yet rigid enough that when the lead reached the heart the barbs would pop back out to their original position. In this way, the barbed lead would become entagled with the trabeculae in the ventricle and less likely to dislodge within the first two or three days of implantation. Schulman contends that he came up with this tined lead design in response to the problem of lead dislodgement. Yet this contention strikes the Court as rather disingenuous because Schulman testified, contrary to his deposition testimony of November 8-10, 1983, that in 1971 and 1972 he considered dislodgement not to be a serious problem. He, in fact, characterized dislodgement to be more like an infection or similar nuisance, but certainly not a serious problem.[15]

Nevertheless, Schulman told of building two different styles of barbed leads prototypes. He described one style of barbed leads as a cloverleaf. The cloverleaf lead had flattened silicone rubber barbs which were petal-like and placed near the electrode tip at either a 90° or 75° angle (*See* PSX 114(3) and (4); *See also* PSX 8b). He described another style of lead as having between two and six tubular barbs which were longer and at a sharper angle, maybe 45°, to the lead body (*See* PSX 114(1) and (2)). Schulman provided a crude sketch of his barbed lead prototypes (PSX 114). These prototype leads were handmade by cutting the

[15]If dislodgement was such an insignificant problem to Schulman, what, then, prompted him to build a prototype of a tined lead and why would he so divert his energies from the development of his precious rechargeable pacemaker?

barbs from room temperature silicone rubber with an Exacto knife and gluing them to an existing commercial endocardial lead with silicone adhesive. He remembers the cloverleaf lead as being the better quality handmade lead because the flattened barbs or petals were easier to slice from silicone rubber wtih a knife.

After building the prototype barbed leads, Schulman tested them in the hearts of living dogs. While Schulman believes that 20 barbed leads were implanted in dogs in 1971, he cites the dog James as being the first recorded implant of a barbed lead. He remembers implanting a barbed lead in James on August 24, 1971 at Harbor General Hospital in Los Angeles with Dr. Criley, the Chief of Cardiology of Harbor General, and James Beazell, the laboratory supervisor. James received a barbed endocardial lead of the cloverleaf variety. Schulman is able to recall the August 24, 1971 implant date of James because of his personal handwritten record of such dog implants (PSX 48). He recalls that a barbed lead was implanted in James because another personal implant record (PSX 35) shows that the purpose of the James implant was "a new lead design." "New lead design" meant barbed lead to Schulman.

The Court, however, wonders whether Schulman's memory and records are perhaps deficient. Neither of these records was prepared contemporaneously with the implant of James. Rather, these records were prepared well after the implant of James. While Schulman believed PSX 48 to have been prepared on February 5, 1973, it was clearly shown that PSX 48 was prepared sometime much later. Similarly, while Schulman believed his notation of "new lead design" in the purpose column of PSX 35 to have been made shortly after November 26, 1973, it was shown that

the notation to PSX 35 could possibly have been made in 1974. Documents and records related to PSX 48 and 35 were also shown to be flawed with numerous inconsistencies, ambiguities, and contradictions. "New lead design," which keyed the barb lead to the James implant in Schulman's mind, was also shown to refer to leads other than barbed leads. For example, Schulman admitted that "new lead design" also referred to a flange lead with a screw-in connector which was being developed at Pacesetter in 1971 and which Schulman sketched for the Court (*See* PX 206; *See also* PX 209). In no Pacesetter record is a structure referred to as a "new lead design" clearly shown to be a barbed lead. Supporting documentary evidence, contemporaneous or otherwise, is completely lacking with respect to Schulman's testimony of a barbed lead inplant in James in August 1971.

James Beazell offered his oral testimony to corroborate Schulman's recollection that a barbed lead had been implanted in James in 1971. Beazell, who has a master's degree in physiology from UCLA, was the supervisor of the cardiology research laboratory at Harbor General Hospital in the early 1970's when Schulman and Dr. Criley were working on the rechargeable pacemaker. While an employee of Harbor General, Beazell worked closely with Dr. Criley and Schulman in the study and development of the rechargeable pacemaker, especially implants and animal testing. Beazell later became a consultant for Schulman and eventually a full-time employee of Pacesetter. In connection with the pacemaker development, Beazell recalled at least three types of barbed leads. First, he remembered an harpoon- or anchor-shaped barbed lead (*See* PSX 103(a)). The second type of barbed lead, he recalled, had four or

more silicone rubber projections coming off the lead body at an acute angle in a spiral fashion *(See* PSX 103(b)). The third type of barbed lead, which was developed much later than the first two barbed leads, was a cloverleaf or umbrella tip lead (*See* PSX 103(c); *See also* PSX 8b). Beazell provided a rough sketch of these barbed leads (PSX 103) for the Court. All of these leads had an electrically conductive tip with soft pliant silicone rubber barbs at an acute angle and away from the lead tip.

Beazell believed that all three types of these barbed leads had been implanted in dogs in the early 1970's. He remembered personally implanting the first barbed lead in James in August 1971 at Harbor General Hospital. The implanted barbed lead was handmade and was either harpoon-shaped or spiral-fashion (*See* PSX 103(a) and (b)). It was not, in direct conflict with Schulman's recollection, a cloverleaf barbed lead because the cloverleaf lead was not developed and implanted until some years later, possibly 1973 or 1974. Beazell remembered that James was implanted with a barbed lead in August 1971 with reference to one of his implant records *(See, e.g.,* 56, 57 and 58). The implant records had both the implant date for James of August 24, 1971 and the notation "new lead design" which meant barbed lead to Beazell. None of the implant records, however, was contemporaneous with the James implant. Beazell, in fact, had no contemporaneous records of any implant of any barbed lead before June 21, 1973. He admitted that the records for James had been lost and had to be reconstructed. Beazell also admitted that these records were often annotated and information, such as dates, changed. Because Beazell's testimony lacks sufficient contemporaneous documentation and because it raises conflicts with

Schulman's testimony, Beazell's testimony falls short of corroborating Schulman's testimony with respect to prior use of a barbed lead.

Gerald Adomian offered his account of the microscopic analysis of dog hearts with Schulman's barbed leads to corroborate Schulman's and Beazell's testimony about barbed leads in dogs in the early 1970's. Adomian is a research scientist with a doctorate in biological sciences from UCLA. He specializes in morphology and is expert with both light and electron microscopes. In December 1971, Schulman approached Adomian with respect to evaluating leads implantetd within a couple of dog hearts. Schulman was concerned primarily with whether the leads were penetrating the wall of the dog hearts. Adomian states that he is well able to remember the events of 1971-72 for three reasons. First, he was defending his doctoral dissertation in January 1972 and, because of his dissertation defense, Adomian was not immediately able to accommodate Schulman in December 1971. Second, Adomian remembers the events of December 1971 because he believes that, after talking to Schulman and considering the problems and difficulties of implanting a pacemaker lead in the heart, he came up with an "interesting" idea of putting barbs at the end of a pacemaker lead.[16] Third, Adomian remembers December 1971 because it was the first time he had ever seen, let alone analyzed, pacemaker leads in an animal heart. He had no previous experience of any kind with pacing.

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[16]Curiously, Adomian mentioned his "interesting" idea of a barbed lead for the first time at trial. It is also curious that Adomian, with no previous experience in pacing or pacemaker leads, was able to come up with this idea in 1971 after a brief conversation with Schulman which dealt primarily with lead penetration of heart tissue. To Adomian's disappointment, however, the dog hearts which Schulman delivered contained leads similar to his idea.

Adomian examined the two dog hearts from Schulman near the end of January 1972. He recalled that the leads in the dog hearts had a conductive wire covered with a polymer ending at an exposed tip. The leads also had four or five flexible silicone rubber barbs near the tip but pointing away from the tip at a 30° to 45° angle. The barbs were pliant yet rigid enough to maintain the angle to the lead body when unrestrained. Adomian believed that, in veiw of the fibrotic process which surrounded portions of the lead tip, that the leads had been implanted in the hearts of living animals for about three months. He did not observe or participate in the lead implants in the living dogs, nor did he see the leads connected to a pulse generator and operating. Unfortunately, Adomian has no written report regarding these barbed leads, no notes of his examination of the dog hearts, no photographs of the leads or the examination, no documents in reference to the leads or the examination, and no tangible evidence of any kind relating to Schulman's barbed leads or the examination of January 1972. Essentially, Adomian offers the Court completely unsupported oral testimony to corroborate the inadequately supported oral testimony of Schulman and Beazell. Adomian's testimony, like Beazell's testimony, fails to corroborate sufficiently Schulman's testimony with respect to prior use of a barbed lead.

Albert Rambo also offered his oral testimony to corroborate Schulman's account of a prior use of a barbed lead in 1971. Rambo joined Pacesetter in July 1971 as an engineering aide whose duties included electroforming, electroplating, and drafting. He remembered that Schulman conducted several in-house classes for Pacesetter employees in which the various aspects of pacing were discussed. Rambo

recalled Schulman talking about a four-barbed lead which was designed to become entangled with the trabeculae. Sometime between July 1971 and May 1972, Rambo remembers, Schulman asked him to photograph a barbed lead. This bipolar lead had a conductor covered with a rubbery material and extending from the lead body and away from the tip at a 45° angle were four barbs of the same rubbery material. The barbs were pliant and flexible. Rambo provided a sketch of the lead which he photographed (*See* PSX 108). Rambo photographed the lead with a tripod-mounted Polaroid camera with a microscope adapter. He returned the lead with the photographs to Schulman. Rambo thinks Schulman put the photographs in an engineering notebook and does not know what Schulman did with the lead.

Rambo also remembers Beazell bringing Schulman a lead still connected to the pulse generator. Schulman had Rambo photograph this lead which differed from the previous lead only in that it was unipolar and had two barbs as opposed to four barbs. Rambo sketched the second lead (*See* PSX 109). Again, Rambo returned the lead and the photographs to Schulman and, again, Schulman put the photographs into an engineering notebook. Rambo does not know what Schulman did with the lead or pulse generator. Rambo photographed no other pacemaker leads for Schulman while at Pacesetter.

Rambo never saw these barbed leads implanted in a dog or human heart. He, in fact, does not know if these leads were ever used. While Rambo is certain that Schulman put the photographs of the leads into a blue spiral binder engineering notebook, he does not know where that notebook is today and it was not produced at trial. Rambo's testimony comes closest to corroborating Schulman's testimony.

Yet Rambo's oral testimony remains unsupported and has failed to convince the Court that Schulman was responsible for a prior use or invention of a barbed lead in 1971.

Pacesetter, in addition to the oral testimony of its witnesses, offered what it considered to be tangible evidence of barbed or tined leads existing before the conception of a tined lead as illustrated in the '501 patent. Pacesetter introduced a single cavity barbed lead mold (PSX 9a) which Les Lettau made at the direction of Harry Fletcher in the Spring of 1972. Pacesetter also introduced the testimony of Schulman, Fletcher, Lettau, Rambo, and Craig to establish the existence and use of a barbed lead mold in 1972. But the testimony with respect to the barbed lead mold, like the testimony with respect to Schulman's conception, construction, and implantation of the barbed lead, is unclear and inconsistent.

Harry Fletcher came to Pacesetter in March 1971 as an engineer of sorts. Fletcher's main job on March 1971 was to develop a lead winding machine, but he also remembers working with Schulman on the development of the lead body. Fletcher recalled that at this time Schulman had spoken to him of developing a lead that would not slip inside the heart of a dog. Schulman designed such a lead styled as a barbed lead for which Fletcher made an aluminum mold. From this mold, Fletcher believes, a couple of dozen prototype barbed leads were made. The lead was coiled wire in a silicone rubber insulation ending in an electrically conductive tip. Extending from the lead body and away from the lead tip at an angle of 30° were soft, pliant silicone rubber barbs. Fletcher sketched this barbed lead (PSX 94). Fletcher also recalled that about 15 barbed leads were made in 1971 at an outside molding company

wtih a transfer mold because Pacesetter did not have transfer molding equipment at that time. He believes that all these leads were implanted in dogs, but he himself witnessed only one implant with Schulman and Beazell in late Summer or early Fall 1971.

Fletcher recalled that in February 1972 Les Lettau came to Pacesetter to do machine work, including making molds. In early 1972, at Fletcher's direction, Lettau made a single cavity barbed lead steel mold (PSX 9a). From this mold were produced two-barbed leads which were similar to PSX 8a. The leads produced had a silicone rubber body ending in an electrically conductive tip. Coming off the lead body at an acute angle were silicone rubber barbs which appeared to hold their shape when unrestrained. Fletcher first saw the single cavity steel mold (PSX 9a), which Lettau made, in March 1972. At that time, the mold, which Fletcher sketched (PX 163), was a transfer mold with two sprues (B and C) and two gates (D and F) serving the main channel or cavity of the mold.[17] Three or four days after receiving this mold from Lettau and before ever using the mold, Fletcher ordered that it be modified. Two more gates (green lines) were added. Because Fletcher could not find an outside firm to do the transfer molding and because Pacesetter did not then have the facilities to do transfer molding, Fletcher had Lettau convert

[17]A transfer mold is, just as its name indicates, a mold into which material is transferred or injected. A pot with material, such as silicone rubber, is positioned on top of the mold and then heated. When the material reaches the appropriate temperature, a ram comes down into the pot and forces the heated material into the mold through the sprues. Sprues are holes in the vertical plane of the mold which provide access for material from outside to inside the mold. The material travels through the sprues into the gates. Gates are small channels in the horizontal plane and parting line of the mold which carry the material from the sprues to the main cavity of the mold. From the gates, the material passes into the cavity of the mold and is cured.

the mold into a compression mold.[18] To convert the mold to a compression mold, the channel or cavity of the mold was extended the length of the mold, the sprues (B and C) and the gates (D and F) were plugged, and the two remaining gates were enlarged to form a barb. Basically, the mold evolved from these two configurations of a transfer mold and compression mold.

Aftr the mold was completed sometime in 1972, Fletcher made a few leads with it. He would take an available commercial lead and center it in the mold so that the ring electrode of the lead rested in the little widening or groove just behind the plugged sprues. He then would put a silicone compound in the cavity, close the mold, and heat it up. Fletcher believes he made leads in this manner and similarly instructed others at Pacesetter. He never observed any of these leads being implanted, nor did he see any test results of these leads. Fletcher, in fact, has no knowledge of whether these leads were ever implanted in a dog.

Leslie Lettau went to work for Pacesetter in February 1972 as a machinist. His first project at Pacesetter was to build an aluminum mold. He built a single cavity four-barbed lead aluminum mold. Lettau's next project was to build a single cavity two-barbed steel mold (PSX 9a). He remembers this mold because he began the mold at the Pacesetter facility on Keswick in Van Nuys and completed it at the new Pacesetter facility in Sylmar in mid-May 1972. This mold, he assumed, was used to produce a two-barbed lead much the same as PSX 8a, but he never actually made a lead with the mold, nor did he see anyone else make a lead with the mold.

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[18] A compression mold is a mold in which material, such as silicone rubber, is placed, often by hand. The two halves of the mold are then combined, pressed, and heated. The molding material is then allowed to cure.

When Lettau first made the mold at the Van Nuys facility, it was a compression mold with a single main channel and two small channels to form barbs (*See* PX 199; *See also* PSX 111(1) and 113). The mold was tried in that form and then he was ordered to convert it to a transfer mold. To convert the mold to a transfer mold, he drilled two sprues (A), two gates (B), and two barb cavities (C) (*See* PX 200; *See also* PSX 111(2) and 113). Lettau gave the transfer mold to Fletcher who soon returned it to Lettau to be reconverted to a compression mold. To reconvert the mold to a compression mold, Lettau effectively had to reorient the mold. He plugged the two sprues (black), filled in the gates and barb channels (green), cut two new barb channels (C), widened the area for the ring electrode placement (A), and drilled three vent holes (1, 2, 3) in the main cavity (*See* 201; *See also* PSX 111(3) and 113). For Lettau, the two-barbed lead steel mold evolved from three configurations.

Mary Craig began working for Pacesetter in January 1973 as a lead person. As a lead person, Craig instructed other employees how to build the mechanical part of the lead. She remembers from January 1973 a number of leads, including a two-barbed lead. The barbed lead had a coil conductor encased in silicone rubber ending in a metal tip assembly. The silicone rubber barbs extended from the lead body away from the tip at approximately a 30° to 45° angle. Craig did not see the two-barbed lead mold (PSX 9a) until June 1973 when she was promoted to supervisor of the leads department. During the Summer of 1973, the two-barbed lead mold was used under her supervision to produce barbed leads. Craig believed that in this time approximately 100 barbed leads were made. At the end of

the Summer of 1973, she gave the mold to the engineering department. Craig did not see the mold again until she was asked to make a barbed lead (PSX 8a) for the purposes of this litigation in November 1983 and January 1985.

In using the two-barbed lead in the Summer of 1973 just as in November 1983 and January 1985, Craig stated that the technician filled the main cavity of the compression mold halves with silicone rubber and placed the existing commercial lead into the cavity. The commercial lead, however, was positioned with the ring-tip electrode in the relief area rather than the main cavity. The mold was then closed and pressed. After removing the mold, the lead was taken from the cavity and the excess silicone rubber or flash was trimmed. The lead was cured in the curing oven and then was ready for finishing touches (*See* PSX 9d(1) and 9d(2)) Albert Rambo also remembered leads being made in this manner from mid-1972 to mid-1973.

The testimony of Fletcher, Lettau, and Craig may establish the existence of a single cavity mold (PSX 9a) at Pacesetter in 1972-73, but their testimony raises more questions than answers with respect to how the mold came to be through its various configurations, how the mold was used in production, and what types of leads were produced from the mold. For example, both Fletcher and Lettau identified the single-cavity mold (PSX-9a) as the final configuration of the mold which they, under the direction of Schulman, designed and built in early 1972. But Fletcher and Lettau do not remember the mold evolving from the various configurations in the same way. Fletcher recalls the mold going through only two configurations, the transfer mold and the compression mold. Yet Lettau specifically recalls the mold going through three configurations, the

compression mold, the transfer mold, and the reoriented compression mold. The two men most actively associated with the development of this rather important single cavity mold cannot agree on how the mold came to be in its final form. Their disagreement is curious because they both emphasized the clarity of their recollection at trial of the events relating to the development of the mold.

Craig also identified the single-cavity mold (PSX 9a) as the final configuration of the mold which she used to make barbed leads in 1973. But Craig used the mold in a manner different from that which Fletcher and Lettau described as its intended manner of use. Craig told of positioning the commercially available lead body in the mold so that the ring-tip electrode rested in the relief area just at the end of the main cavity of the mold. Both Fletcher and Lettau, on the other hand, said that the ring-tip electrode of the lead was intended to rest in a small specially grooved area of the main cavity of the mold. Craig, Fletcher, and Lettau were each clear in their own way on where the lead body was to be positioned and how the mold was to be used. That Craig's use of the mold differed from that which Fletcher and Lettau, the designers and builders of the mold, intended is interesting because it suggests that the use of the mold and its resulting product are not necessarily limited by the apparent or intended design of the mold. Rather, the user of the mold has some play to fashion a lead in a desired configuration even though the mold design might not readily lend itself to the lead configuration that the user desires.

The testimony of and exhibits related to Fletcher, Lettau, and Craig also raise questions with respect to exactly what types of leads could have been produced from the

mold and what types of leads were actually produced from the mold. A source of these questions was a three-cavity wedge tip lead mold of Pacesetter (PX 165). Lettau stated at trial, contrary to his deposition testimony of January 4, 1985, that he was sure he made this three-cavity mold in July and August 1972.[19] Lettau now remembers that he build the three cavity mold (MX 165) shortly after the single-cavity mold (PSX 9a) in May 1972. Lettau also remembers that the three-cavity mold was used exclusively to make wedge tip leads, not barbed leads. Fletcher and Craig confirmed that the three-cavity mold was used to make wedge tip leads. Comparing the single-cavity mold to the three-cavity mold, the Court finds that the molds are not dissimilar. The molds, in fact, share a number of features common to a transfer mold, including similarly located sprues, gates, and injection holes in the main channel or cavity. The most noticeable difference between the

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[19]Lettau's testimony at trial was often at odds with testimony from his January 4, 1985 deposition or statements in his August 22, 1983 affidavit. In addition to remembering at trial, but not at his deposition, that he made the three-cavity mold (PX 165), Lettau remembered the various configurations of the single-cavity mold (PSX 9a) differently than at his deposition two months earlier. Lettau also had difficulty reconciling his trial testimony with statements in his affidavit. For example, in his August 22, 1983 affidavit (PX 195), Lettau stated that he made the molds for tined leads, including a two-barbed lead (C) and a eight-barbed lead (D), in the Spring of 1972. But, as Lettau admitted at trial, the two-barbed lead he described and pictured in his affidavit was, in fact, a two-barbed cupped lead made in 1975 and not even in existence in 1972. Similarly, the eight-barbed lead he described in his affidavit could not have been made in 1972 because the mold was not made until possibly 1975 or 1976. Lettau attempted to smooth these inconsistencies by saying that the tined leads described and pictured in his affidavit were intended only to illustrate the concept of a tined lead. The affidavit, however, does not lend itself to this reading. Lettau's testimony also suggested that the photograph (E) of the single-cavity mold (PSX 9a) included in his affidavit was attached after he signed the affidavit. Lettau's testimony, when viewed in light of his deposition testimony and affidavit statements, raises questions of credibility with respect to both Lettau and Pacesetter.

two molds, other than the plugged sprues and gates in the single cavity mold, is the tip configuration. The tip of the lead in the single-cavity mold was straight shanked and the tip of the lead in the three-cavity mold was wedged. The similarities between the two molds point to the not so unreasonable possibility that the single-cavity mold was once intended and crudely built to produce straight shank leads through the transfer mold process. The three-cavity mold which followed shortly was a more refined attempt at the transfer mold process intetnded and built to produce wedge tip leads. The Court is not convinced that the single-cavtiy mold (PSX 9a) was expressly intended, designed, constructed, and used to produce Schulman's two-barbed lead.

In reaching this conclusion, the Court does not ignore Fletcher's testimony that the single-cavity mold was intended to produce two-barbed leads, or Craig's testimony that she observed and personally used the single-cavity mold to produce two-barbed leads. Rather, the Court notes, as Craig's testimony illustrates, that a mold can be used in various ways to arrive at a desired lead configuration. Just as Craig worked within the limitations of the mold to position a ring-tip electrode as she desired, one can work within the limitations of the same mold to produce a barbed lead if desired. The single-cavity mold was not shown to have been exclusively designed and constructed to produce a barbed lead. The single-cavity mold could have been designed and constructed to produce a lead other than a barbed lead. Yet, a barbed lead can be made from the single-cavity mold, just as Craig did *(See* PSX 9d(1) and 9d(2)). Whether the lead from this mold, in fact, has barbs or just excess silicone rubber or flash from the gates which was not trimmed from the lead body is an open question—a ques-

tion which Pacesetter has not answered clearly to the satisfaction of the Court. In failing to convince the Court that the lead from the single-cavity mold actually had barbs and not untrimmed excess silicone rubber, the possibility remains that the single-cavity mold was first a straight shank lead mold and then, when necessary or convenient, a barbed lead mold. The single-cavity mold (PSX 9a) is, therefore, tangible evidence of questionable significance with respect to Schulman's claim of inventing and using a barbed lead in 1971 and 1972 before the conception of a tined lead as disclosed in the '501 patent.

The Court has carefully considered the testimony and evidence relating to Schulman's claimed prior use and invention in 1971 and 1972 of a barbed endocardial lead. The testimony of Pacesetter's witnesses, especially Schulman, Beazell, Fletcher, and Lettau, is replete with contradictions and inconsistencies, when read both individually and jointly. The frequency and severity of these contradictions and inconsistencies leaves the Court with serious misgivings about the credibility and trustworthiness of Pacesetter's witnesses. The related evidence of prior use and invention, such as the implant records and steel molds, did not allay the Court's misgivings. Rather, this related evidence, which was intended to corroborate and bolster the testimony of Pacesetter's witnesses, served to obscure and further confuse the testimony because it lacked contemporaneousness and reliability. Because the contradictions and inconsistencies in the testimony and evidence are so glaring and the credibility and trustworthiness of Pacesetter's witnesses so wanting, the Court seriously questions whether Schulman ever conceived of a barbed endocardial lead before the invention date, let alone the patent application

date, of the tined endocardial lead disclosed in the '501 patent. Pacesetter has failed to convince the Court that Schulman even conceived of a barbed endocardial lead prior to the critical date.

Even if the Court were to assume that Shulman did conceive of a barbed endocardial lead prior to the critical date, Pacesetter has failed to convince the Court that such a lead was reduced to practice. Such a barbed lead (be it two-barbed or cloverleaf, depending on the Pacesetter witness) was never shown to have been sufficiently tested to demonstrate that it would work for its intended purpose of passively fixing a pacemaker lead within the human heart.[20] At most, Schuman's barbed lead was shown only to have been in an experimental or testing stage of development and, then, only in dogs. While dogs are an invaluable research medium providing a human-like heart and generating important data, which may well indicate the likelihood of success in human beings, implants of barbed leads in dogs alone cannot suffice for a reduction to practice of a barbed lead. Reduction to practice of a barbed or tined lead must be accomplished through implantation in the human heart. Pacesetter could not show satisfactorily that Schulman's barbed lead was demonstrated to work in a dog heart and could not possibly show that Schulman's barbed lead was demonstrated to work in a human heart. Pacesetter has

[20]The intended purpose of a barbed or tined endocardial lead is to fix passively a pacemaker lead within the ventricles or right atrial appendage of the heart by cooperating with the trabeculae so as to enhance reliable and stable positioning of the lead against the heart wall permitting natural fixation or fibrosis to occur, and to lessen the attendant risks of lead dislodgement and tissue penetration. Because the pacemaker is intended, designed, and marketed primarily, if not exclusively, for the therapeutic implantation in a human being, the intended purpose of a tined endocardial lead contemplates passive fixation within the human heart.

failed to convince the Court that Schulman's barbed endocardial lead was reduced to practice.[21]

Even if the Court were to assume that Schulman did conceive of a barbed endocardial lead prior to the critical date and that such a barbed lead was reduced to practice, Pacesetter cannot convince the Court that use of such a lead was a public use. Pacesetter makes much of the fact that its experiments were conducted in an area with unusual and frequent public access, that its employees and consultants were not required to maintain any official secrecy obligations with respect to the barbed lead, and that Schulman freely showed his barbed lead to prospective employees and visitors. But these circumstances do not amount to a meaningful and beneficial disclosure to the public as is inherent in a public use. Pacesetter's use of Schulman's barbed lead was nothing more than experimental and, presumably, subject to alterations and improvements. To the extent the use of Schulman's barbed lead was experimental and within the exclusive control of Pacesetter, the use was not a public use resulting in the disclosure of new and useful information. The Court has considered the circumstances of the use of Schulman's barbed lead, and, taken as a whole, these circumstances do not support a conclusion that the use of Schulman's barbed lead was a public use. Pacesetter cannot convince the Court that any use of Schulman's barbed lead was a public use.

The Court has carefully examined the testimony of the witnesses and the related evidence with respect to prior use

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[21] Because the Court, assuming that Shulman conceived of a barbed endocardial lead, finds that such a barbed lead was not reduced to practice, the Court need not reach the issue of abandonment, suppression, or concealment under § 102 (g), for, technically, no invention existed to be abandoned, suppressed, or concealed.

and prior invention. Just as the Court was not convinced that the '501 patent was anticipated by publication, especially the Vitatron reference, the Court is not convinced that the '501 patent was anticipated by prior use or prior invention. The Court, in fact, has doubts whether Schulman even conceived of a barbed lead which could have been the subject of use or invention in 1971 and 1972. Even if Schulman did conceive of a barbed lead, however, it was never shown to have been reduced to practice or subjected to a public use. The '501 patent was not shown to have been anticipated by publication, prior use, or prior invention. Pacesetter has failed to persuade the Court by clear and convincing evidence that the '501 patent was anticipated under § 102.

§ 103

Section 103 provides that:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103.

The issue under § 103, therefore, is whether the invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. Several

basic factual inquiries must be made under § 103, including the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Obviousness or nonobviousness is determined against the background of these factual inquiries. *Id.* Secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others, may also have relevancy as indicia of obviousness or nonobviousness. *Id.* at 17-18. When a patent is challenged on the ground that the claimed invention would have been obvious under § 103, all evidence relevant to the issue of obviousness must be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (citing *In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983)).

The first factual inquiry to be made under § 103 is the scope and content of the prior art. "The scope of the prior art has been defined as that 'reasonably pertinent to the particular problem with which the inventor was involved'." *Id.* at 1535 (quoting *In re Wood*, 599 F.2d 1032, 1036 (C.C.P.A. 1979)). Factors to be considered in determining the scope or relevance of the prior art include the type of skill required to understand the disclosure of the patent in suit, as well as the type of art which the PTO applied to the claims. *Orthopedic Equipment Co., Inc. v. United States*, 702 F.2d 1005, 1008 (Fed. Cir. 1983).

The particular problem with which Citron was involved in 1972 was the development of an endocardial pacemaker lead with a means of passive fixation to reduce the incidence of lead dislodgement in the ventricles and right atrial appendage and to lessen the risk of tissue penetration or damage in the veins and heart chambers. An indication of

the scope of the prior art or the art reasonably pertinent to this problem is the prior art which the PTO cited and applied in the prosecution of the '501 patent. The PTO, in processing the application for the '501 patent, cited and applied a variety of prior art patents[22] and prior art publications.[23] The scope of these prior art references included both pacemaker leads and catheter-like devices in general. That the PTO cited and applied prior art references involving pacemaker leads and catheter-like devices is not surprising in light of the type of skill required to understand the disclosure of Claim 1 of the '501 patent. A rudimentary knowledge of pacemater leads and catheter-like devices, as well as a familiarity with the physiology and anatomy

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[22]Prior art patents which the PTO cited in connection with the '501 patent include:

U.S. Patent		
No. 2,854,983 (Baskin)	(Inflatable Catheter)	(PX 4)
3,348,548 (Chardack)	(Implantable Electrode with Stiffening Stylet)	(PX 5)
3,397,699 (Kohl)	(Retaining Catheter Having Resiliently Biased Wing Flanges)	(PX 6)
3,516,410 (Hakim)	(Cerebro-Ventricular Catheter)	(PX 7)
3,568,659 (Karnegis)	(Disposable Percutaneous Intracardiac Pump and Method of Pumping Blood)	(PX 8)
3,608,555 (Greyson)	(Radioopaque and Optically Transparent Tubing)	(PX 9)
3,717,151 (Collett)	(Flesh Penetrating Apparatus)	(PX 10)
3,719,190 (Avery)	(Heart Stimulation Electrode with a Conical Positioning Parachute)	(PX 11)
3,815,608 (Spinosa et al)	(Retaining Catheter)	(PX 12)
3,835,864 (Rasor et al)	(Intra-Cardiac Stimulator)	(PX 13)

[23]Prior art publications which the PTO cited in connection with the '501 patent include:

M. Schaldach, *New Pacemaker Electrodes,* 17 American Society for Artificial Internal Organs 29-35 (1971) (translation) (PX 14);

U. Wende and M. Schaldach, *Neue intrakardicle Schrittmacher-elektrode,* 95 Deutsche Medizinische Wochenschrift 2026-2028 (Oct. 1970) (PX 15 (with translation));

H. Pieper, *Registration of Phasic Changes of Blood Flow by Means of a Catheter-Type Flowmeter;* 29 The Review of Scientific Instruments 965-67 (Nov. 1958) (PX 16).

of the human heart and vascular system, would be necessary to understand the disclosure of Claim 1 of the '501 patent. The scope of the prior art or the prior art which is reasonably pertinent to the particular problem that Citron faced in 1972 would include pacemaker leads and catheter-like devices.

The content of the prior art includes the reference which the PTO cited and applied during the prosecution of the '501 patent and the uncited references which Daig and Pacesetter introduced at trial. With respect to the references which the PTO cited and applied, Daig and Pacesetter rely principally on the Schaldach article (PX 14), the Portsmann article (DX 57), the Rasor-Spickler patent (PX 13), the Avery patent (Pg 11), the Collett patent (PX 10) and the Hakim patent (PX 7). With respect to the references which the PTO did not cite, Daig and Pacesetter rely on the Fountain patent (PX 127), the Klieman patent (PX 19), the Vitatron article (PSX 10b), the Rasor-Spickel article (PX 22), the Schaldach German patent (PSX 10d) and the Medtronic flange or wedge tip leads, Models 6901 and 6907 (PX 30 and DX 40).

The Schaldach article, M. Schaldach, *New Pacemaker Electrodes,* 17 American Society for Artificial Internal Organs 29 (1971) (translation) (PX 14), which the PTO cited and applied in the prosecution of the '501 patent, discloses an atrial sensing catheter electrode. This atrial catheter electrode is designed for the stable fixation of the sensing electrode tip in the right atrial appendage, but may also be used in the ventricles. The atrial catheter electrode is made of a silicone rubber insulated helical coil of elgiloy which terminates in a cylindrical elgiloy tip or elgiloy wire hooks turned in a relief loop, not unlike a safety pin (*See* PX 14,

Figure 11). The catheter electrode has these fine wire hooks in order to assure stable fixation and to maintain permanent contact with the endocardium of the atrial appendage or ventricles. The fine wire hooks are covered with a guiding catheter or tube until the electrode is properly positioned. The guiding tube is then removed and the fine wire hooks are released and spring into place. The fine wire hooks are intended to anchor firmly between the trabeculae of the atrial appendage or the ventricles.

The Schaldach German patent, German Patent No. 2,-053,919 (PSX 10d (with translation)), which was not before the PTO in the prosecution of the '501 patent, makes virtually the same disclosure as the Schaldach article (PX 14). The Schaldach German patent discloses a cardiac pacemaker electrode, which is made of a coiled wire lead enclosed in an insulating jacket of silicone rubber, terminating in an electrode tip of reverse metal wire hooks (*See* PSX 10d, Figures 1 or 2). This cardiac pacemaker electrode is designed to improve stable fixation of the electrode against the wall of the atrial appendage or ventricles. The reverse wire hooks, which remain in a catheter until release is appropriate, are intended to ensure fixation by engaging the trabeculae of the appendage or ventricles.

The Portsmann article, W. Portsmann, J. Witte, et al, *P Wave Synchronous Pacing Using Anchored Atrial Electrode Implanted Without Thoracotomy*, 30 The American Journal of Cardiology 74 (July 1972) (DX 57), which was cited in the background of the invention in the '501 patent, discloses the same atrial sensing electrode as the Schaldach article (PX 14) and the Schaldach patent (PSX 10d). That the disclosure is the same is not very surprising since Schaldach was one of the co-authors of the Portsmann article.

This sensing electrode, which may be used in both the atrial appendage and ventricles, consists of an elgiloy spiral encased in a silicone rubber insulator terminating in an electrode tip of two fine elgiloy wire hooks or barbs which form a relief loop (*See* DX 57, Figure 1, p. 75; *See also* PX 14, Figure 11, p. 34, and PSX 10d, Figure 2). The two fine wire hooks or barbs of this "fishhook" electrode, which are in the applicator catheter until release, are designed to anchor securely the electrode tip to the trabeculae of the atrial appendage or ventricles.

The Rasor-Spickler patent, United States Patent No. 3,835,864 (PX 13), which the PTO cited and applied in the prosecution of the '501 patent, discloses a wholly self-contained intracardiac stimulator intended for use as a pacemaker. This self-contained pacemaker consists of an elongated capsule-like body covered with a smooth inert material, such as stainless steel, containing a nucleonic or biologically-activated power source. The forward end of this capsule-like body is provided with a pair of oppositely directed, spiral stainless steel wires as means for attaching the pacemaker to the myocardium (*See* PX 13, Figures 1 and 4). These stainless steel tissue-attaching wires or barbs are retained in a retracted position close to the pacemaker body in the sheath until desired positioning of the pacemaker is accomplished, and then the barbs are released springing out to the expanded or operative position. The wires or barbs are literally screwed into the myocardium through clockwise rotation. The pacemaker, with its barbs imbedded in the myocardium, is intended to wedge in the trabeculae. While it is suggested that the device be used in the right ventricle, it may be used in any of the four chambers of the heart.

The Rasor-Spickler self-contained pacemaker may also be modified to function as an endocardial electrode. The modified device acting as an electrode consists of the same capsule-like body, which serves as a means of electrical contact, but without the pulsing circuitry or power source. The electrode itself is connected to the pulse generator by a flexible electrical lead. This electrode device has means of attachment slightly different from that of the self-contained pacemaker. The means of attachment for the electrode device consists of a pair of wires attached to the electrode body and extending rearwardly and outwardly (*See* PX 13, Figure 12). These retaining or attachment wires remain in a sheath until proper positioning is accomplished and the sheath is retracted. The wires then imbed themselves within the heart muscle. The general technique of inserting and implanting this electrode does not differ significantly from that of the self-contained pacemaker.

The Rasor-Spickler article, J. Spickler, N. Rasor, et al, *Totally Self-Contained Intracardiac Pacemaker*, 3 Journal of Electrocardiology 325 (1970) (PX 22), which the PTO did not cite in the prosecution of the '501 patent, discloses the same self-contained intracardiac pacemaker as the Rasor-Spickler patent (PX 13). The Rasor-Spickler article is merely a report on the development and progress of the research on the feasibility of the self-contained intracardiac pacemaker.

The Avery patent, United States Patent No. 3,719,190 (PX 11), which the PTO did cite and consider in the prosecution of the '501 patent, discloses a flexible heart stimulation electrode with a conical parachute. This electrode device consists of a flexible wire lead, such as stainless steel or platinum, covered with an insulating material, such as

teflon, terminating in an electrode tip or contact made of a physiologically inert metal, such as platinum. Near the electrode tip is a soft, yet resilient, conical parachute made of a physiologically inert and sterilizable material, such as silicone rubber. The apex of this conical parachute is adjacent and directed to the electrode tip. *(See* PX 11, Figure 2) This electrode device is intended to be placed in the heart by insertion through a vein. The device can be easily passed through a cannula into a vein because the parachute is soft enough to be compressed along the lead body. When the device leaves the cannula and enters the vein, the parachute returns to its original conical position. The conical parachute is intended to be caught and swept along in the blood flow drawing the electrode device into the heart. The device may be withdrawn from the heart with a light pull which causes the parachute to invert permitting unimpeded removal. The soft flexible parachute is designed not to damage venal tissue during insertion and removal of the device.

The Collett patent, United States Patent No. 3,717,151 (PX 10), which the PTO cited and applied in the prosecution of the '501 patent, discloses a flesh-penetrating apparatus which provides access to an interior cavity of the body of an animal. This flesh-penetrating apparatus is a medical device which employs a trocar[24] and a cannula[25] to create a drainage outlet from an interior cavity to the body exterior. The cannula, with the trocar inside of and extending or telescoping from it, is inserted through the tissue until the device reaches the body cavity. The trocar is then removed providing an outlet or vent from the body cavity to the ex-

[24]A trocar is a sharp pointed surgical instrument or stylet which is used to insert a cannula through tissue into a body cavity.

[25]A cannula is a tube which is inserted into the body and provides access from the body exterior to a body cavity.

terior. Attached to the end of the cannula by a hinge mechanism are a plurality of radially extendable plastic fingers. During insertion, the plastic fingers abut or lie against the cannula. Upon insertion into the cavity, the plastic fingers are released or extended radially to form a 90° angle with the longitudinal axis of the cannula. The extended fingers come into contact with the wall of the body cavity and serve to hinder the dislodgement of the cannula in the direction of the body exterior. During removal, the fingers are allowed to pivot about 90° or collapse along the cannula to a position similar to, but in a direction opposite of, that upon insertion (*See* PX 10, Figures 1, 3, and 5). While the device is designed to be used with a trocar to penetrate the tissue for insertion into a body cavity, it may be used without a trocar for insertion through an existing opening, such as the mouth, nose, ear or blood vessel, into a cavity.

The Hakim patent, United States Patent No. 3,516,410 (PX 7), which the PTO cited and applied in the prosecution of the '501 patent, discloses a ventricular catheter for use with ventriculo-atrial shunting devices.[26] This ventricular catheter consists of a tube made of a soft, tissue-compatible material, such as silicone rubber, with a plurality of radially extending membranes or discs of the same material attached to the catheter at regular intervals and near the end of the catheter. Between the membranes or discs and in the wall of the tubing are drainage apertures (*See* PX 7, Figures 1 and 2). The ventricular catheter is inserted through brain tissue en route to a ventricular cavity. During insertion, the soft, flexible membranes or discs collapse against the catheter. Upon reaching the ventricular cavity, the membranes

[26]A ventriculo-atrial shunt or shunting device is a medical device which allows cerebrospinal fluid to drain from the ventricles of the brain into the venous system.

or discs return to their normal upright and radial position. The membranes or discs on this ventricular catheter serve to keep the drainage aperatures free of material that could plug them and to keep the catheter and its apertures from coming into direct contact with the ventricular walls.

The Fountain Patent, United States Patent No. 3,492,996 (PX 127), which the PTO did not cite in the prosecution of the '501 patent, also discloses a ventriculo-atrial shunt. This device consists of a thin, flexible catheter, preferably made of silicone rubber, which is positioned in a cranial ventricle. The ventricular end of this shunt device is connected to a pump mechanism, which pumps the cerebrospinal fluid from the cranial ventricle to the vascular system, located under the scalp. Attached to the pump is a telescoping catheter which leads subcutaneously to the atrial end of the shunt. The atrial end of the shunt is positioned within the atrium of the heart through a venal insertion. A plurality of slightly upwardly directed, wing-like projections are located adjacent to the atrial end of the shunt (*See* PX 127, Figure 6). These projections or wings are flexible and bend upward to allow easy passage through the vein to the atrium without damage or scarring to the venal tissue. These projections or wings are intended to retain and center the device within the atrium and center the device in the vein should the device be pulled from the atrium.

The Klieman patent, United States Patent No. 3,635,223 (PX 19), which the PTO did not cite in the prosecution of the '501 patent, discloses an embolectomy catheter. This apparatus consists of an outer guiding cannula and an inner catheter. The outer cannula is made of a nonreactive, nontoxic, and nontraumatic material, such as polyvinylchloride. The inner catheter, which is actually the emboli-

extracting instrument, has a soft, flexible distal tip with an inflatable latex, vinyl, or other elastomeric materal balloon adjacent the distal tip. The balloon itself has a plurality of rounded and flexible barbs or protrusions slanting away from the distal tip of the catheter at a 30° to 60° angle. The protrusions on the balloon are sufficiently rounded and flexible to avoid damage to the vascular system, but firm enough to hold onto the clot. (*See* PX 19, Figure 1). The apparatus, with the emboli-extracting catheter inside the outer catheter, is insered through a vein, such as the femoral vein, and guided through the vena cava and right side of the heart to the pulmonary artery and the site of the embolus or clot. The distal end of the cannula is positioned close to the clot. The inner catheter is then pushed out of the cannula and through and past the clot. The inner catheter is pulled back through the clot and the protrusions on the balloon of the distal tip engage the clot and draw it into the cannula for removal. This operation may be repeated until the entire clot is removed. When the size of the vein or clot requires, the balloon may be inflated to increase its diameter to effect removal of the clot.[27]

The Vitatron article, *Pacemaker Electrode*, 4 Bio-Medical Engineering 383 (August 1969) (PSX 10b), which the PTO did not cite in the prosecution of the '501 patent, dis-

[27]The parties dispute the effect that uncited prior art found in the classes and subclasses which the examiner searched in connection with the '501 patent, such as the Fountain patent and Klieman patent, has in carrying the burden of persuasion with respect to invalidity. As the Court has noted, that burden may be carried more easily when the prior art which was not cited is more pertinent than the prior art which was cited. The Court has carefully examined the Fountain patent and Klieman patent, and finds that neither patent is more pertinent than the prior art which was cited. At most, the Fountain patent is equally pertinent to the cited art, and the Klieman patent is less pertinent than the cited art. Consequently, the uncited art makes Daig's and Pacesetter's difficult burden of persuasion with respect to invalidity no easier.

closes an intra-cardiac pacemaker electrode. This pacemaker electrode consists of a helically coiled elgiloy lead insulated by a tube of silicone rubber and a platinum-iridium electrode tip. The electrode tip is fitted with "a small barbed silicone ring." The ring at the electrode tip is intended to prevent electrode dislocation in the critical postoperative period.

Flange or wedge tip endocardial leads *per se*, especially Medtronic Models 6901 and 6907 (PX 30 and DX 40), were not before the PTO during the prosecution of the '501 patent. A flange or wedge tip lead consists of an electrical conductor encased in an insulating material inert to body fluids, such as silicone rubber, ending in an exposed electrically conductive electrode tip. Adjacent the electrode tip is a small wedge- or flange-shaped projection made of the same insulating material, silicone rubber, as the lead body (*See* PX 30). The flange or wedge tip lead is intended to cooperate with the ventricular apex or the trabeculae of the heart to effect stable fixation. Flange or wedge tip leads, however, could not have been unknown to the PTO because such leads were mentioned specifically in the background section of the '501 patent, as well as in the Smyth article and the Portsmann article referred to in the background section. Additionally, the Schaldach article (PX 14), which the PTO cited and considered, specifically refers, in word and diagram, to flange or wedge tip leads.

The second factual inquiry under § 103 is to ascertain the differences between the prior art and the claims at issue. Although findings on the differences between the prior art and the claims at issue are required under *Graham*, the issue under § 103 is not whether the differences themselves would have been obvious. *Stratoflex, Inc. v. Aeroquip*

Corp., 713 F.2d 1530, 1537 (Fed. Cir. 1983). Rather, the consideration of differences, like each of the factual inquiries set forth in *Graham*, is but an aid in determining the issue of whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *Id.*

The Schaldach references, the Schaldach article (PX 14), the Schaldach German patent (PSX 10d), and the Portsmann article (DX 57),[28] disclose an atrial sensing catheter electrode. Although this catheter electrode is an endocardial lead which consists of an electrical conductor encased in a material generally inert to body fluids terminating in an exposed electrically conductive electrode tip, it differs significantly from the device disclosed in the '501 patent in that it lacks soft and pliant nonconductive tine means which cooperate with heart tissue to hold the electrode tip in position and prevent penetration of heart tissue. The Schaldach device teaches the use of flexible conductive wire hooks or barbs as a means of lead fixation within the heart and as an integral component of the electrode tip. What the Schaldach device teaches in terms of lead fixation is effectively active fixation. The fine wire hooks are intended to anchor in the trabeculae of the right atrial appendage or ventricles. Although anchoring itself may not readily connote active fixation, it takes on that connotation when seen in the light of the nature of the fine wire hooks of the device and Schaldach's related instructions concerning the use of a guiding catheter during the insertion and retraction of the device to

[28]The Portsmann article (DX 57) is also a Schaldach reference because it discusses the results of a new technique for the transvenous implantation of an atrial sensing electrode which was the same Schaldach device as disclosed in the Schaldach article (PX 14) and the Schaldach German patent (PSX 10d).

avoid tissue damage or penetration.[20] The Schaldach device does not teach passive fixation through cooperation with heart tissue, as does the '501 device. Rather, the Schaldach device teaches active fixation through anchoring in the heart tissue, if not penetration of the heart tissue.

What the Schaldach device teaches in terms of the electrode tip is that the fine wire hooks which anchor the lead are an integral component of the conductive system of the electrode tip. The fine wire hooks are themselves the means by which the electrical impulse is transmitted to the heart tissue. That the fine wire hooks are conductive is essential to the operation of the Schaldach device. The lengthy discussion of metal behavior, surface area, short-circuits, conductivity, and electrochemical reactions in the Schaldach references underscores the importance of wire hooks in the Schaldach device. To the extent the Schaldach device teaches the use of conductive wire hooks, it teaches away from the nonconductive tine means adjacent the electrode tip of the '501 patent device.

The Rasor-Spickler references, the Rasor-Spickler patent (PX 13) and the Rasor-Spickler article (PX 22), disclose an intra-cardiac stimulator which may be used as either a self-contained pacemaker or an electrode assembly to be connected to a conventional endocardial pacing lead. Both Rasor-Spickler devices teach the use of a pair of stainless steel points or wires located at the forward end of the elec-

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[20]Schaldach, in fact, referred to this electrode tip with fine wire hooks as a "dangerous tip" which requires the use of a guide catheter "to avoid injuries by the fine wires" and to accomplish "danger-free positioning and removal." U. Wende and M. Schaldach, *Neue intrakardiale Schrittmacherelektrode*, 95 Deutsche Medizinische Wochenschrift 2026, 2026 (Oct. 1970) (PX 15 with translation). Schaldach advises in implanting the electrode that "[t]o be avoided in every case is pulling back the unprotected electrode, since otherwise the fine papillary muscles can be injured." *Id.* at 2027.

trode body as a means of fixation. The self-contained pacemaker has the two stainless steel wires in an oppositely directed spiral configuration. The electrode assembly has the two stainless steel wires extending rearwardly and outwardly from the forward end of the body. Both Rasor-Spickler devices teach active fixation with the stainless steel wires. That the Rasor-Spickler devices teach active fixation can be seen in the language used to describe the steel wires —"tissue- or body-attaching members," "anchor portions," and "attaching points or wires"—and the process by which the steel wires fix the devices in the heart—"attachment," "imbedded," and "forcible retention." The Rasor-Spickler devices, like the Schaldach device, require the use of a protective sheath during insertion to prevent the steel wires from damaging or penetrating venal tissue. The Rasor-Spickler devices do not teach passive fixation through cooperation with heart tissue or the prevention of tissue penetration by means of soft and pliant nonconductive tine means, as does the device of the '501 patent. The Rasor-Spickler devices, instead, teach away from soft and pliant nonconductive tine means with steel wires designed as a means of active fixation to attach to and imbed in, and not cooperate with, heart tissue.

The Avery patent (PX 11) discloses a heart stimulation electrode with a conical parachute. The Avery device, which is an endocardial lead consisting of an electrical conductor encased in a material generally inert to body fluids ending in an exposed electrically conductive electrode tip. is significantly different from the device disclosed in the '501 patent. The Avery device does not teach the use of soft and pliant nonconductive tine means for lead fixation through cooperation with heart tissue or prevention of tissue damage

or penetration. The Avery device teaches the use of a soft and pliant conical parachute located near the electrode tip as a means of catching or being drawn into the flow of blood in order to pass the electrode assembly and lead through the vein into the heart chambers. The Avery device teaches only a technique of transvenous implantation of an endocardial lead. The Avery device teaches nothing of the fixation of an endocardial lead, let alone the fixation of an endocardial lead by means of soft and pliant nonconductive tines which cooperate with, yet prevent penetration of, heart tissue.

The Collett patent (PX 10) discloses a flesh-penetrating apparatus. The Collett device differs significantly from the device of the '501 patent. The Collett device is not an endocardial lead, but rather a cannula which serves as a vent from a body cavity to the body exterior. The Collett device does not teach the use of soft and pliant, yet sufficiently rigid, nonconductive tine means at a generally acute angle to the lead or catheter body which are intended to cooperate with, and not penetrate, heart tissue to hold the lead tip in position. The Collett device, however, does teach the use of hard plastic fingers hinged to the body of the cannula as a means of preventing dislodgement of the cannula in the direction of the body exterior. The hinged fingers, which are not unlike a toggle joint, serve not so much as a means of fixing the cannula in the body cavity as a means of retaining the cannula in the body cavity. The hinged fingers, to the extent that they act like a toggle joint, rest against the tissue of the wall of the body cavity to retain the cannula, but do not cooperate with the tissue to fix the cannula. The hinged fingers are capable of three positions which are accomplished mechanically and not as a result of the mater-

ial of which the fingers are made. The Collett patent does not teach the passive fixation of an endocardial lead within the heart, as does the device disclosed in the '501 patent.

The Hakim patent (PX 7), which discloses a cerebroventricular catheter, also differs significantly from the device of the '501 patent. The Hakim device is not an endocardial lead and does not teach the use of soft, pliant, nonconductive tines as a means of fixation through cooperation with heart tissue. The Hakim device, instead, teaches the use of soft, flexible, radial membranes near the end of the catheter as a means of preventing plugging of the catheter apertures and spacing the catheter from the walls of the ventricles. It is neither designed nor intended to be fixed in position through the cooperation of heart tissue. The Hakim device, unlike the device of the '501 patent, teaches nothing of fixation.

The Fountain patent (PX 127), which discloses a ventriculo-atrial shunt, is quite similar in teaching to the Collett patent (PX 10) and differs from the device of the '501 patent for essentially the same reasons as the Collett patent. The Fountain device is not an endocardial lead, but a ventricular shunt. Although the Fountain device teaches the use of flexible, upwardly directed, wing-like projections near the outlet end of the device, it does not teach the use of these projections as a means of fixation. Rather, the Fountain device, like the Collett device, teaches the use of these projections as a means of retaining the shunt in the atrium in much the same way as a toggle joint. The Fountain device also teaches the use of these projections as a means of spacing the shunt from the atrial wall upon placement and centering the shunt in the vein during insertion. The wing-like projections of the Fountain device are designed to rest

against the atrium wall to retain the device in a centered position, but not actually cooperate with the heart tissue. To the extent that the Fountain device teaches the use of wing-like projections as a means of retaining the device in a centered position in the atrium like a toggle joint, the Fountain device, like the Collett device, teaches away from the use of such flexible projections as a means of passively fixing the electrode tip of an endocardial lead in position through cooperation with heart tissue.

The Klieman patent (PX 19) discloses an embolectomy catheter which also differs significantly from the device of the '501 patent. The Klieman device is simply an inner catheter, which is actually the emboli-extracting instrument, covered by an outer cannula. The Klieman device teaches the use of an inflatable balloon with rounded, flexible barbs near the distal tip of the catheter as a means of engaging and removing emboli in the vascular system. These rounded, flexible barbs are intended not to fix the device in the vascular system, but merely to engage the emboli without damaging the surrounding vascular tissue. The Klieman device, unlike the device of the '501 patent, teaches nothing of fixing the electrode tip of an endocardial lead in position against the wall of the heart through the cooperation of nonconducting tine means with heart tissue.

The Vitatron article (PSX 10b) discloses an intracardiac catheter electrode which is an endocardial electrode with a helically coiled electrical conductor encased in silicone rubber terminating in an exposed electrically conductive electrode tip. The Vitatron device differs from the device of the '501 patent in that the Vitatron device has an electrode tip fitted with "a small barbed silicone ring." The '501 device has an electrode tip fitted with soft, pliant nonconductive

tines. As the Court has noted, the term "a small barbed silicone ring" is itself ambiguous and alone teaches nothing. Reading the term "a small barbed silicone ring" in the spirit of the Vitatron article suggests that the Vitatron device has some means of fixation located near the electrode tip. Precisely what kind of fixation means the Vitatron device has, however, cannot be discerned from reading the article alone. The term "a small barbed silicone ring" suggests that the electrode tip of the Vitatron device has a ring which is small, which is barbed, which is silicone, and which is different from the structure of the electrode tip of the device of the '501 patent. That "a small barbed silicone ring", as determined from other references, is likely a flange or wedge tip lead corroborates the difference between the device of the Vitatron article and the device of the '501 patent.

The flange or wedge tip leads (PX 30 and DX 40) are endocardial leads with an electrical conductor encased in a material generally inert to body fluids terminating at an exposed electrically conductive electrode tip. The flange or wedge tip leads differ from the endocardial lead of the '501 patent in terms of fixation means. The flange or wedge tip leads teach the use of a small flange- or wedge-shaped projection made of the same insulating and inert material as the lead body located near and pointing away from the electrode tip as a means of lead fixation. The flange or wedge tip leads teach passive fixation through wedging the electrode tip with this projection into position in the heart, most often in the right ventricular apex which has a uniquely accommodating shape for this lead design. The projection on the electrode tip of the flange or wedge tip leads were intended primarily to achieve passive fixation by tak-

ing advantage of the complementary muscle structures of the heart, such as the ventricular apex, until fibrosis could occur. The flange or wedge tip leads, of course, often also engaged the trabeculae until fibrosis could occur. The nonconducting tines of the '501 device, on the other hand, were intended primarily to achieve passive fixation by taking advantage of the muscular structures in the heart, such as the trabeculae. The flange or wedge tip leads, unlike the '501 device, do not teach the use of nonconducting tines as a means of passive fixation to hold the electrode tip in position through cooperation with and not penetration of the heart tissue.

The third factual inquiry to be made is the level of ordinary skill in the art. Factors that may be considered in determining the level of ordinary skill in the art include: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology involved; (5) the educational background of those actively working in the field; and (6) the educational background of the inventor. *Orthopedic Equipment Co., Inc. v. United States,* 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting *Jacobson Brothers, Inc. v. United States,* 512 F.2d 1065, 1071 (Ct. Cl. 1975)). Secondary considerations under *Graham,* such as commercial success and failure of others are also invaluable real-life indicia of the level of skill in the art. *Id.* Essential to this inquiry, however, is "adher[ence] to the statute, *i.e.,* to hold that an invention would or would not have been obvious, as a whole, when it was made, to a person of 'ordinary skill in the art'—not to the judge, or to a layman, or to those skilled in remote arts, or to geniuses in the art at hand." *Environmental Designs,*

Ltd. v. Union Oil Co., 713 F.2d 693, 697 (Fed. Cir. 1983), *cert. denied*, 104 S.Ct. 709 (1984).

The Court has considered various factors, especially the educational background of those actively working in the field and the educational background of the inventors, in determining the level of ordinary skill in the art of endocardial pacemaker lead design in 1972. The Court finds that the level of ordinary skill in the art of endocardial pacemaker lead design in 1972 was not particularly high, and certainly not as high as Pacesetter and Daig would have the Court believe. A person of ordinary skill in the art in 1972 would have had a master's degree in electrical or mechanical engineering coupled with a basic knowledge of the physiology and anatomy of the heart and vascular system.

Secondary considerations, such as commercial success, long felt need, failure of others, copying, and widespread recognition of the significance of the invention in the industry, are relevant indicia of obviousness or nonobviousness, and must be considered when present. *Simmons Fastener Corp. v. Illinois Tool Works*, 739 F.2d 1573, 1575 (Fed. Cir. 1984), *cert. denied*, 105 S.Ct. 2138 (1985); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Objective evidence of nonobviousness, or the *Graham* indicia, "may in a given case be entitled to more weight or less, depending on its nature and its relationship to the merits of the invention. It may be the most pertinent, probative, and revealing evidence available" on the issue of obviousness. *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983), *cert. denied*, 105 S.Ct. 172 (1984). A nexus between the merits of the claimed invention and the evidence

of secondary considerations, however, is required in order for the evidence to be given substantial weight in determining the issue of obviousness. *Simmons Fastener Corp. v. Illinois Tool Works,* 739 F.2d 1573, 1575 (Fed. Cir. 1984); *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530, 1539 (Fed. Cir. 1983).

Secondary considerations raised in the evidence at trial included commercial success, contemporaneous or simultaneous invention, long felt need, and failure of others. Commercial success was perhaps the most sharply contested secondary consideration. Medtronic attempted to show that its endocardial tined pacing leads have enjoyed tremendous commercial success which is directly attributable to the invention as expressed in the '501 patent. Medtronic attempted to show the success of the tined leads with reference to its own sales of tined leads,[30] as well as sales of tined leads in the industry as a whole. Medtronic claims that its domestic tined leads sales have grown from two percent of total lead sales in Fiscal Year 1977, when its first tined lead, Model No. 6950/6951, was introduced, to more than 70 percent of total lead sales today (*See* PX 109). Medtronic also claims that the pacemaker leads industry as a whole has focused its attention on and realized greater sales of tined endocardial leads, as a perusal of the advertising of any respectable pacing trade publication will indicate (*See*,

[30]In assessing commercial success, Medtronic did not distinguish between sales of individual models of tined leads and tined leads as a whole. For Medtronic, all of its tined leads, Model Nos. 6950/6951, 6961/6962, 6971/6972, 6990, 6991, 6991U, 6993, 4002, 4502, 4012, and 4512, include soft, pliant, nonconductive tine means for cooperating with heart tissue to hold the lead tip in position in conformance with the '501 patent. Although specific tine length and location may vary with lead model, Medtronic contends that these leads are the equivalent of the tined endocardial lead disclosed and described in the '501 patent, and, therefore, the sales of these tined leads are relevant to the commercial success of the tined endocardial lead.

e.g., PX 40). Every manufacturer and supplier of pacemaker leads, according to Medtronic, now sells tined leads. As an example, Medtronic cites the pacemaker lead sales records of Pacesetter. Pacesetter's sales of tined leads, according to Medtronic, have grown from no sales in 1978 to 98 percent of total domestic lead sales and 97 percent of total domestic and international lead sales in 1984 (*See* PX 181). As another example of how the pacemaker leads industry has accepted the tined endocardial lead, Medtronic offered the licensing agreements of the '501 patent and the schedule of royalties received from Cardiac Pacemakers, Inc. (CPI) and Cordis Corporation (Cordis) (*See* DX 38, DX 39, and PX 154).[31] Medtronic believes that the tined endocardial lead, as disclosed in the '501 patent, has enjoyed commercial success.

In a further attempt to show commercial success, Medtronic claimed that its tined endocardial leads overcame great skepticism in the medical community to become the lead of choice. Medtronic offered the testimony of Dr.

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[31]On October 19, 1984, Cordis brought suit against Medtronic in the United States District Court for the Southern District of Florida. Cordis sought declaratory judgment of the invalidity of United States Patent Nos. 3,902,501 and 3,939,843, and the invalidity of the license agreement between Cordis and Medtronic involving those patents. Cordis also sought a preliminary injunction enjoining Medtronic from terminating its license agreement with Cordis during the pendency of this action, and the establishment of an interest bearing escrow account for the receipt of royalty payments due under the license agreement during the pendency of this action. Medtronic moved to dismiss Cordis' declaratory judgment complaint, or, in the alternative, to transfer the action to the United States District Court for the District of Minnesota. On January 10, 1985, Cordis' Motion For Establishment of Escrow Fund and for Preliminary Injunction, and Medtronic's Motion to Transfer were granted.

The action, *Cordis Corporation v. Medtronic, Inc.*, Civil No. 4-85-138, is now before the United States District Court for the District of Minnesota. Daig moved on January 28, 1985 to consolidate the issues of the '501 patent validity and infringement in the Cordis litigation with the Medtronic Daig/Pacesetter litigation, but the Court refused to consolidate the actions so close to the eve of trial.

James Maloney to illustrate this point. Dr. Maloney is a cardiologist specializing in clinical electrophysiology and clinical pacing at the Cleveland Clinic in Cleveland, Ohio, where he is the director of the electrophysiology laboratory. He has been with the Cleveland Clinic since 1981, and before then he was with the Mayo Clinic in Rochester, Minnesota. Dr. Maloney actually instituted the clinical electrophysiology program and practice at the Mayo Clinic Dr. Maloney stated that the tined endocardial lead was received initially with reservation and uncertainty at the Mayo Clinic. Dr. Maloney and his colleagues at the Mayo Clinic, in fact, were offered the opportunity in 1975-76 to do clinical testing on the first Medtronic tined lead, Model No. 6950/6951, but declined the opportunity. Dr. Maloney and his colleagues did not consider the tined lead to be a viable alternative in endocardial pacing at that time. Physicians at the Cleveland Clinic and other larger pacing centers on the East Coast of the United States, according to Dr. Maloney, had even greater reservations and uncertainties about the tined endocardial lead. Not until the clinical testing and implant data demonstrated the efficacy of the tined lead did Dr. Maloney, his colleagues, and other physicians accept the tined lead. Dr. Maloney now believes the tined lead to be the most popular endocardial lead and lead of choice in the medical community today. Dr. Maloney's own experience at the Cleveland Clinic today shows that 99.5 percent of endocardial leads used in the ventricles are tined leads, and 70 percent of endocardial leads used in the atrium are tined leads with the remaining 30 percent being screw-in leads. Dr. Maloney is so convinced of the efficacy of the tined endocardial lead that he believes a physician who implants a flange or wedge tip lead today, when the physician

has a choice between a wedge tip lead and a tined lead, is acting unethically. To implant a lead with a simple wedge and no tines, according to Dr. Maloney, is not proper medical practice in the light of the available information. Medtronic believes that the endorsement of the tined lead as the lead of choice in the medical community today is evidence of the commercial success of the tined endocardial lead as disclosed in the '501 patent.

Daig and Pacesetter attemptetd to counter Medtronic's claim of tremendous commercial success of its tined endocardial leads. Daig and Pacesetter sought to establish that no nexus existed between the claimed commercial success of Medtronic and the presence of soft, pliant, nonconductive tines on these endocardial leads. Daig and Pacesetter initially point to the first commercial tined ventrical lead of Medtronic, Model Nos 6950/6951. For Daig and Pacesetter, Model Nos. 6950/6951 provide the most significant indication of the commercial success of a Medtronic tined endocardial lead because they were essentially the same leads as the existing wedge tip leads, except for the tines. Model Nos. 6950/6951 are also perhaps the most significant indication of the commercial success for Daig and Pacesetter because Model Nos. 6950/6951 themselves were not successful. As Dr. Maloney's testimony indicated, physicians in 1976 were skeptical and questioned the viability of a tined endocardial lead due in part to the size, shape, and location of the tines which were rather long. Medtronic did not begin to realize any commercial success on its tined leads until it redesigned Model Nos. 6950/6951 to form Model Nos. 6961/6962 with short, stubby tines closer to the lead tip. According to Daig and Pacesetter, that Model Nos. 6950/6951, which were the only

Medtronic leads to provide a "pure" comparison between new tined leads and existing wedge tip leads, were commercially unsuccessful prevents Medtronic from demonstrating the required nexus between the commercial success of other later tined leads with additional features and tines on these leads. Commercial success of any Medtronic tined lead, Daig and Pacesetter conclude, cannot be demonstrated.

Daig and Pacesetter also attempted to limit the significance of the greater acceptance and sales of later Medtronic tined endocardial leads. Daig and Pacesetter sought to attribute any success of later tined leads to features of the leads other than tines. For example, Daig and Pacesetter sought to attribute the success of Model Nos. 6961/6962, which followed Model Nos. 6950/6951, to a variety of features other than tines, including a Multi-Filar conductor coil and a ring tip electrode. Daig and Pacesetter also suggested that the success of later tined leads was attributable to the improved implantation technique of surgeons. No one feature of these later tined endocardial leads, especially tines, could be determined to be the primary reason for the commercial success of these later Medtronic tined leads, according to Daig and Pacesetter. Because no nexus could be established between the acceptance and sales of these later tined leads and the existence of tines themselves, Daig and Pacesetter conclude that Medtronic cannot show commercial success of its tined lead.

As a final attempt to counter any claim of commercial success of Medtronic tined leads, Pacesetter offered the testimony of Dr. Irving Plotkin. Dr. Plotkin is a Vice President of Arthur D. Little, Inc., and a Director of its valuation subsidiary. He is a microeconomist who specializes in

the analyses of the effects of various types of government regulation, self-regulation, and taxation on capital flows, output, prices, risk-taking, competition, and efficiency within individual industries. Dr. Plotkin, who has been with Arthur D. Little, Inc. since 1968, has designed, directed, and conducted research for a variety of prominent clients in both the public and private sectors. Dr. Plotkin stated that, based on the data which Pacesetter presented to him Medtronic could not demonstrate that tines in themselves accounted for the sales of Medtronic tined leads. Additionally, Dr. Plotkin stated that Medtronic could not demonstrate commercial success with respect to any tined endocardial lead which he considered to be a product innovation. Dr. Plotkin defined commercial success of a product innovation to be an aggressive growth in market share. Dr. Plotkin found that Medtronic could not show its tined leads to be commercially successful because Medtronic failed to realize an aggressive growth in market share, but rather realized a decrease in market share, and because Medtronic's sales of tined leads tended to cannibalize its existing endocardial lead market. In arriving at this conclusion, Dr. Plotkin found significant the market results of Medtronic Model Nos. 6950/6951 because they were the only leads which allowed him to assess the effect of tines alone on lead sales. All later Medtronic leads, such as Model Nos. 6961/6962, combined other features or improvements with tines which, in his opinion, presented multiple and indistinguishable causes of acceptance and sales of Medtronic tined leads. Consequently, Daig and Pacesetter argue, the Medtronic tined leads cannot be shown to be a commercial success.

The Court has considered the evidence with respect to

commercial success, and although the Court is not prepared to accept Medtronic's conclusion that its tined leads enjoyed tremendous commercial success, the Court is similarly not prepared to accept Daig's and Pacesetter's conclusion that the Medtronic tined leads enjoyed absolutely no commercial success. The Court, however, is satisfied that the Medtronic tined leads have enjoyed sufficient commercial success to suggest the nonobviousness of the tined endocardial lead disclosed in the '501 patent. In so concluding, the Court is not aware of Daig's and Pacesetter's concern that Medtronic tined leads should not be viewed as generic devices with tines, but rather individual devices with varied features and improvements other than tines. The Court is also not unaware of the possible influence that some of these varied features and improvements, such as a Multi-Filar coil and a ring tip electrode, may have had on tined lead sales. But the Court is satisfied that the primary reason Medtronic tined leads sold was the presence of soft, pliant, nonconductive tines. The Court notes that Dr. Maloney, an amply qualified and credible expert in pacing, testified that the presence of tines on an endocardial electrode is the major factor in deciding whether to select a lead. Dr. Maloney stated that if he were offered a lead with improvements such as a Multi-Filar coil and a ring tip electrode but no tines, he would reject it outright because of the absence of tines as a means of passive fixation.[32] Tines, for Dr. Maloney, are a necessary, if not indispensable, com-

[32]Doctor Maloney gave an example of such a rejection of a non-tined lead during his tenure at the Mayo Clinic. In 1978, Dr. Maloney and his colleagues at the Mayo Clinic were presented with a new porous tip, Multi-Filar coil lead without tines. They attempted to use the lead in clinical study but encountered major problems with dislodgement. They subsequently abandoned the clinical study of that lead until the manufacturer provided tines on that lead.

ponent of an endocardial lead designed to remedy the most significant and difficult problem of endocardial pacing, acute lead dislodgement. The Court is satisfied that the commercial success of the Medtronic tined leads is causally linked to the presence of tines on these leads and the advantages inherent in such tines as disclosed in the '501 patent.

In reaching the conclusion that the Medtronic tined lead has enjoyed some commercial success, the Court is not unmindful of Dr. Plotkin's conclusion to the contrary. Dr. Plotkin was an amply qualified and credible expert microeconomist, and his conclusion with respect to the commercial success of the tined lead was rooted deeply in economic theory and the capital market standard. His reliance on economic theory, however, perhaps so skewed his reasoning as to limit its applicability in terms of commercial success for purposes of this patent action. Dr. Plotkin defined commercial success for the tined lead, which he considered a product innovation, to be an aggressive growth in market share. He could find no commercial success for Medtronic tined leads because the tined leads showed no aggressive growth in market share, and, in fact, the tined leads appeared to cannibalize Medtronic's existing endocardial lead market.[33] Dr. Plotkin's definition and analysis

[33]Even accepting Dr. Plotkin's pure economic definition and analysis of commercial success, the Court wonders whether cannibalizing the existing market, in this instance, actually goes to show lack of commercial success. Dr. Plotkin believed that the Medtronic tined lead lacked commercial success because it tended to cannibalize the existing market for Medtronic straight shank and wedge tip leads. But would not a product innovator, such as Medtronic, desire that its innovation, the tined lead, cannibalize the existing market when the innovation is intended or designed to render obsolete those products which currently occupy the market? If not from an economic standpoint, at least from a medical standpoint, one would hope that a product innovation which so enhances the existing product as to render the existing product obsolete would cannibalize the existing market.

of commercial success focused clearly, if not exclusively, on the economic effect of the product innovation, the tined lead, on the product innovator, Medtronic. Dr. Plotkin's definition and analysis of commercial success did not look to the effect, of any kind, of the product innovation on the industry as a whole. Such a definition and analysis could lead to the conclusion that a product innovation *per se* was not a commercial success, but the same product innovation nonetheless had a profound influence on the industry and market. That conclusion may well be what Dr. Plotkin offered the Court. In a pure economic analysis, using, as Dr. Plotkin described it, the "tough" capital market standard, the Medtronic tined lead was probably not commercially successful. In a rather pragmatic analysis, however, looking to a pacing industry which now intensively markets tined leads, and to a medical community which now regards tined leads as leads of choice, the Medtronic tined lead was commercially successful. The Court is satisfied that Medtronic has shown that its tined leads, which embody the advantages inherent in the endocardial lead disclosed in the '501 patent, have enjoyed sufficient commercial success to suggest nonobviousness.

Daig and Pacesetter also offered evidence of contemporaneous invention as a secondary consideration which suggests obviousness. Daig and Pacesetter attempted to show that Schulman at Pacesetter, Hess at Cordis, and Rasor and Spickler at the Cox Heart Institute had independently invented a tined endocardial lead at approximately the same time as Citron and Dickhudt. The Court finds the evidence completely lacking to support these claims of contemporaneous invention. Daig and Pacesetter have failed to demonstrate to the satisfaction of the Court that Schul-

man, Hess, and Rasor and Spickler even conceived of an endocardial lead with soft, pliant, nonconductive tines, let alone reduced such a lead to practice. Daig and Pacesetter were unable to support their claims of contemporaneous invention with reliable and contemporaneous documents, records, or other physical evidence. The evidence which Daig and Pacesetter offered to show contemporaneous invention and obviousness actually tends more to show the lack of contemporaneous invention and nonobviousness.

Particularly revealing, with respect to the failure of Daig and Pacesetter to demonstrate contemporaneous invention, is the failure of the claimed contemporaneous inventors to have realized and acknowledged their inventions. Schulman, who claimed to have invented a tined lead in 1971 at Pacesetter, dismissed the significance of such a lead. Apparently, Schulman's tined lead failed to gain significance as the years passed because Pacesetter began purchasing all its tined leads from Daig in 1978, and Schulman said not a word. One would think that Schulman would have at least mentioned to Pacesetter that he had invented some seven years earlier the tined lead which Pacesetter intended to purchase from Daig. Similarly, Hess, who claimed in his deposition to have invented a tined lead in 1973 at Cordis, failed to make any bench tests or clinical tests, animal or human, of the tined lead. Instead, Hess placed the samples of the tined lead in a box to be forgotten on a shelf at Cordis. Apparently, Hess' tined lead was forgotten because Cordis entered into a licensing agreement with Medtronic to manufacture the tined endocardial lead in 1982. Again, one would think that Hess would have mentioned to Cordis that he had invented some nine years earlier the tined lead which was the subject of the license agreement between

Medtronic and Cordis.[34] Rasor and Spickler, who claimed to have invented a tined lead in 1969 at the Cox Heart Institute, did not envision a tined lead equivalent to that disclosed in the '501 patent. Rasor and Spickler, in fact, rejected radiating metal fingers, which were as close to soft, pliant, nonconductive tine means as Rasor and Spickler came, as a means of fixation for endocardial leads from 1970 through 1976. Daig and Pacesetter failed to demonstrate satisfactorily any semblance of contemporaneous invention so as to suggest the obviousness of the tined endocardial lead disclosed in the '501 patent.

Medtronic also offered evidence of long felt need as a secondary consideration which suggests nonobviousness. Medtronic attempted to show that its tined endocardial leads satisfied a long felt need in the medical community. Acute lead dislodgement, according to Dr. Maloney, was the most significant problem encountered in the implantation of endocardial pacing leads in the early 1970s. The existing endocardial leads, primarily the straight shank lead and wedge tip lead, would all too frequently slip or dislodge before fibrosis could occur to fix naturally the leads within the heart. The existing endocardial leads, especially the wedge tip, also tended to penetrate or work through the heart tissue upon implantation. Because of the problems of acute lead dislodgement and heart penetration inherent in the existing endocardial leads, a felt need existed to remedy these problems. The Medtronic tined leads, which embodied the advantages inherent in the device disclosed in

[34]Of course, both Pacesetter and Cordis, had they known that their employees had invented a tined lead, may still have chosen to go outside the company for the right to produce or for production of the tined lead for economic reasons. The point remains, however, that neither Pacesetter nor Cordis was given the option or made aware that their employees had already made such leads.

the '501 patent, satisfied this felt need, according to Dr. Maloney. The Court finds that a felt need existed in the early 1970's for an endocardial lead with reduced lead dislodgement and heart penetration characteristics. The Court further finds that the Medtronic tined leads satisfied this need. Although the Medtronic tined leads may not have had as a spectacular or profound impact in the medical community as Medtronic would have the Court believe, the Court is convinced nonetheless that the Medtronic tined leads satisfied a felt need sufficient to suggest nonobviousness.

Medtronic also offered evidence of failure of others as a secondary consideration which suggests nonobviousness. Medtronic attempted to show, with special reference to the work and prior art of Schaldach and Rasor and Spickler, that others had failed in the early 1970's to develop an endocardial lead with a passive means of fixation which was less prone to dislodgement and penetration. As the work and prior art of Schaldach and Rasor and Spickler reflects, they tried a variety of fixation or attachment techniques in an effort to enhance the utility of the endocardial lead. None of them, however, recognize the advantages of soft, pliant, nonconductive tines as a means of passive fixation which was less likely to dislodge or penetrate heart tissue. The work of Schaldach and Rasor and Spickler, which typifies some of the work of the early 1970's, indicates that while the advantages of fixation in the trabeculae were recognized or desired, active fixation continued to be guiding influence in the design of fixation means for endocardial leads. Even discounting the active fixation nature of the Schaldach and Rasor and Spickler work, their work still posed the real threat of penetration. To the extent that the

work of Schaldach and Rasor and Spickler does not reflect a recognition of the inherent advantages of soft, pliant, nonconductive tines as a means of fixation, it tends to show that they failed to develop a means of passive fixation which would reduce acute lead dislodgement and heart penetration. This failure tends to suggest the nonobviousness of the tined endocardial lead which is disclosed in the '501 patent.

The question of obviousness, as the Court of Appeals for the Federal Circuit has acknowledged, is simple to ask, but difficult to answer. *Orthopedic Equipment Co., Inc. v. United States,* 702 F.2d 1005, 1012 (Fed. Cir. 1983). The difficulty in answering this question is due in no small part to the strong temptation to resort to and rely on hindsight in formulating the answer. Hindsight, however, is quite improper when resolving the question of obviousness. To use the patent in suit as a guide through the morass of prior art references, combining the right references in the right way to arrive at the result of the claims in suit, is, therefore, also quite improper. *Id.* Combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination, cannot establish obviousness. *ACS Hospital Systems, Inc. v. Montefiore Hospital,* 732 F.2d 1572, 1577 (Fed. Cir. 1984). The test remains whether the claimed invention as a whole would have been obvious to a person having ordinary skill in the pertinent art at the time the invention was made. 35 U.S.C. § 103. The test, as applied in this action, is whether a tined endocardial lead, as claimed in the '501 patent, would have been obvious to a person having ordinary skill in the art of endocardial pacing lead design in July 1972.

The Court has attempted diligently to make the basic factual inquiries under § 103, as *Graham* requires, and to

examine the results of those inquiries. The Court has also examined the evidence of secondary considerations. Upon full consideration of all the evidence, the Court finds that the invention claimed in the '501 patent would not have been obvious to a person having ordinary skill in the art at the time the invention was made. None of the prior art references, either alone or in combination, would have taught, disclosed, or suggested to a person of ordinary skill in the art the use of soft, pliant, nonconductive tines as a means of passive fixation for cooperating with heart tissue to hold the lead tip in position without penetrating the heart tissue. The evidence of secondary considerations also suggests that the invention claimed in the '501 patent was not obvious. To find otherwise would reveal the Court succumbing to the temptation of hindsight for it is hindsight which entices and deceives in this analysis. Without resort to hindsight, Daig and Pacesetter cannot show the claimed invention of the '501 patent to be obvious. Daig and Pacesetter have failed to persuade the Court by clear and convincing evidence that the invention claimed in the '501 patent would have been obvious to a person having ordinary skill in the art at the time the invention was made.

§ 112

Section 112 provides in relevant part that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
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> * * *

35 U.S.C. § 112.

The relevant portion of § 112 requires that the inventor provide an enabling description of the invention, the best mode which the inventor contemplates for the invention, and a distinct claim or claims of the subject matter which the inventor regards as the invention. To satisfy the enabling requirement of § 112, a patent must contain a description that enables a person skilled in the art to make and use the claimed invention. *Atlas Powder Co. v. E.I. Du Dont de Nemours,* 750 F.2d 1569, 1576 (Fed. Cir. 1984) (citing *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 (Fed. Cir. 1983)). That some experimentation is necessary to make and use the invention does not preclude enablement. *Id.* (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983), and *In re Angstadt,* 537 F.2d 498, 503 (C.C.P.A. 1976)). The amount of experimentation needed, however, must not be unduly extensive. *Id.*

The question with respect to enablement is whether the disclosure in the specification of the '501 patent is sufficient to enable a person skilled in the art to practice the claimed invention. Pacesetter attempted to show that the specification of the '501 patent was not enabling in at least two ways. First, the '501 patent specification was not enabling because it failed to provide adequate information from which to design a workable lead. That detailed information was not provided in the specification with respect to lead body

diameter, tine diameter, tine length, tine location, and tine flexibility, according to Pacesetter, precludes enablement. Pacesetter believes this information to be critical and without such information the '501 patent specification cannot enable. The Court, however, finds that a person skilled in the art of endocardial lead design would find the disclosure in the '501 patent specification sufficient with which to make and use a tined endocardial lead. Although the information which Pacesetter seeks is important, it is not necessarily critical. A person skilled in the art, who would presumably have a basic knowledge of the physiology and anatomy of the heart and vascular system, would be able to deduce this information from the available knowledge of the structure of the heart and endocardial leads.

The second way in which Pacesetter attempted to show that the '501 patent specification was not enabling was that it would take an unreasonable amount of experimentation to get from the patent specification to a working tined lead. Although some experimentation would certainly be necessary to go from the specification to a working tined lead, that experimentation would not be unduly extensive or unreasonable for a person skilled in the art. If, however, a person would want to go from the specification to a commercially acceptable and marketable tined lead, then extensive experimentation would be needed. But the specification need not, and often cannot, disclose a finished commercial product or embodiment. Experimentation related to producing a commercially acceptable product, therefore, cannot defeat an enabling specification. A person skilled in the art would be able to go from the specification to a working tined lead without undue experimentation. The Court finds that the specification of the '501 patent would

enable a person skilled in the art of endocardial pacing lead design to make and use the claimed invention of a tined endocardial lead.

To satisfy the best mode requirement of § 112, the inventor must set forth the best mode of practicing the invention know to the inventor at the time the patent application was filed. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556 (Fed. Cir. 1984). Even if a better mode of carrying out the invention exists and the inventor fails to disclose it, the best mode requirement may still be satisfied if the inventor does not know of or appreciate the better mode. *Id.* For a disclosure to fail to set forth the best mode, it must be shown that the quality of the disclosure is so poor as to result effectively in concealment. *Matter of Application of Sherwood,* 613 F.2d 809, 816 (C.C.P.A. 1980). The best mode disclosed need not necessarily be the optimum mode of carrying out the invention *Plastic Container Corp. v. Continental Plastics,* 607 F.2d 885, 897 (10th Cir. 1979).

The question with respect to best mode is whether the inventors adequately disclosed the contemplated best mode in the specification of the '501 patent. Both Daig and Pacesetter attempted to show that Citron and Dickhudt failed to disclose the best mode of practicing the invention which they knew at the time the patent application was filed. Daig and Pacesetter point to Citron's laboratory notebook (PX 42). Although the laboratory notebook contains the sketch of the tined lead which was disclosed in the '501 patent *(See* PX 42, p. 50), it also contains a photograph of a prototype tined lead which was not disclosed in the '501 patent *(See* PX 42, p. 51). This photograph, according to Daig and Pacesetter, represents the best mode which

Citron and Dickhudt contemplated at the time of the '501 patent application. Daig and Pacesetter also point to the correspondence between Dr. Smyth and Citron from March to May 1973 which involved various improvements in the design of the tined lead *(See,* e.g., PSX 22b and 22c). These improvements, which included increasing tip exposure, repositioning the vertex of the tines, and moving the tines closer to the lead tip, were incorporated into Citron's tined lead, but were not disclosed in the '501 patent application in July 1973. The tined lead with these improvements, according to Daig and Pacesetter, was the best mode contemplated at the time of the '501 patent application. Daig and Pacesetter believe that, because the '501 patent discloses neither the photograph of the prototype tined lead from Citron's notebook, nor the improvements discussed in the correspondent between Dr. Smyth and Citron, the '501 patent fails to disclose the best mode of practicing the invention.

The Court, however, finds that the '501 patent does disclose the best mode which Citron and Dickhudt contemplated at the time of the '501 patent application. It is true that both the prototype photograph and the discussed improvements were not expressly disclosed in the '501 patent. Yet it is also true that both Citron and Dickhudt were not aware that the prototype photograph and discussed improvements represented the best mode of their invention at the time of the patent application. Rather, the most that could be said, at the time of the '501 patent application, was that a variety of experiments and tests were being conducted with respect to the prototype tined lead in the photograph and the improvements discussed between Dr. Smyth and Citron. The prototype photograph and the discussed im-

provements may seem to represent a much better mode than that disclosed in the '501 patent. But that conclusion, in which both Daig and Pacesetter join, is the result of hindsight as focused by the evolution of the tined endocardial lead which has occurred in the 12 years since the '501 patent application. What seems today to have been a better mode then matters not. What matters is the best mode which Citron and Dickhudt contemplated for their invention when they applied for a patent. That Citron and Dickhudt contemplated the prototype tined lead in the photograph and related improvements to be the best mode of their invention at the time of their patent application was not shown. The Court concludes that the specification of the '501 patent sets forth the best mode, which Citron and Dickhudt contemplated at the time of the '501 patent application, of carrying out their invention.

To satisfy the definiteness or distinctly claiming requirement of § 112, the claims must make clear the subject matter which they embrace and so make clear the subject matter from which they preclude others. *Application of Conley,* 490 F.2d 972, 975 (C.C.P.A. 1974). It is a requirement of precision and definiteness intended to point out what the invention is in contradistinction to the prior art and to define the scope of protection of the patent. *In re Vamco Machine and Tool, Inc.,* 752 F.2d 1564, 1577 n. 5 (Fed. Cir. 1985). If the scope of the subject matter which the claim embraces is clear, and if the inventor has not indicated that a claim of a different scope is intended, then the claim does particularly point out and distinctly claim the subject matter which the inventor regards as the invention. *Application of Conley,* 490 F.2d 972, 975 (C.C.P.A. 1974).

The question with respect to definiteness is whether the claim language is sufficiently precise and definite so that one can readily determine if one would infringe the claim. The Court finds that the language of Claim 1 of the '501 patent is sufficiently precise and definite. Although Claim 1 of the '501 patent, like any patent, contains some words of degree and function, such as adjacent and means, the claim language does not lack definiteness. A person of ordinary skill in the art would understand the claim language when the claim is read in light of the same specification. Because a person of ordinary skill in the art would understand what is claimed in Claim 1 of the '501 patent, the Court finds that Claim 1 particularly points out and distinctly claims the subject matter which Citron and Dickhudt regarded as their invention.

The Court has carefully considered the evidence with respect to the requirements of § 112, especially, enablement, best mode, and definiteness. The Court finds that the specification of the '501 patent would enable a person skilled in the art to make and use the invention, that the specification of the '501 patent does set forth the best mode which the inventors contemplated of carrying out their invention, and that Claim 1 does particularly point out and distinctly claim the subject matter which the inventors regard as their invention. Daig and Pacesetter have failed to convince the Court by clear and convincing evidence that the '501 patent does not satisfy the enablement, best mode, and definiteness requirements of § 112.

The question remaining for the Court is whether all the evidence establishes that the challengers of the validity of the '501 patent, Daig and Pacesetter, have carried the burden which § 282 imposes on them so as to have persuaded

the Court that the '501 patent can no longer be accepted as valid. The Court finds that Daig and Pacesetter have failed to carry this burden of persuading the Court of invalidity by clear and convincing evidence. The Court, therefore, continues to accept the '501 patent as valid.

INFRINGEMENT OF THE '501 PATENT

Burden of Proof

The patent owner has the burden of showing by a preponderance of the evidence that the accused device infringes the patent. *Hughes Aircraft Co. v. United States,* 717 F.2d 1351, 1361 (Fed. Cir. 1983). Whether an accused device infringes a valid patent requires resort in the first instance to the words of the claim which define the metes and bounds of the patent right. *Graver Tank & Mfg. Co. v. Linde Air Products Co.,* 339 U.S. 605, 607 (1950).[35] If the accused device falls clearly within the claim, literal infringement is made out. *Id.* If, however, the accused device does not fall clearly within the claim and literal infringement is not made out, then the doctrine of equivalents comes into play. Under the doctrine of equivalents, an accused device which does not literally infringe a claim may still be found

[35]The patented invention as reflected in the language of the claims must first be defined. *Envirotech Corp. v. Al George, Inc.,* 730 F.2d 753,758, 221 USPQ 473, 477 (Fed. Cir. 1984). "Words in a claim 'will be given their ordinary and accustomed meaning, unless it appears that the inventor used them differently'." *Id.* at 759, 221 USPQ at 477 (quoting *Universal Oil Products Co. v. Globe Oil & Refining Co.,* 137 F.2d 3, 6, 58 USPQ 504, 508 (7th Cir. 1943)). The specification and drawings of a patent may also be used in interpreting the claims, but the claims are not limited in scope to any particular mode for practicing the invention that is described in the specification or drawings. *Lockheed Aircraft Corp. v. United States,* 553 F.2d 69, 79 (Ct. Cl. 1977) (citations omitted). Once the claims are defined, whether the claims cover the accused device must be determined. *Envirotech Corp. v. Al George, Inc.,* 730 F.2d 753, 758 (Fed. Cir. 1984).

to infringe "if it performs substantially the same function in substantially the same way to obtain the same result." *Id.* at 608. Whether an accused device is an equivalent is determined with reference to the patent, the prior art, and the particular circumstances of the case. *Id.* at 609.[36]

Claim 1 of the '501 patent, as the Court has discussed, contemplates an improvement to an endocardial lead which comprises:

> nonconducting tine means extending from said encasing material and away from said tip from a location adjacent said tip for cooperating with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said encasing material and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.

(PX 1, column 6, lines 56-66).

The language of the claim is fairly straightforward and lends itself to an ordinary and commonsense meaning. Claim 1 speaks of nonconducting tine means which are barbs and projections. The tine means are located adjacent or near the electrode tip. The tine means extend from the lead body and away from the electrode tip forming an acute angle with the lead body. The tine means are intended to

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[36] "Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect. In determining equivalents, things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be equivalents." *Graver Tank & Mfg. Co. v. Linde Air Products* Co., 339 U.S. 605, 609 (1950).

cooperate with heart issue, such as the trabeculae, to hold the electrode tip in position against the heart wall. The tine means are made of a material inert to body fluids, such as silicone rubber or polyurethane, which is sufficiently rigid to maintain the acute angle of the tine means in relation to the lead body when unrestrained, yet sufficiently pliant to prevent penetration or perforation of heart tissue.

Daig Tined Endocardial Leads

Medtronic offered four Daig tined endocardial leads as accused devices falling clearly wiithin Claim 1 of the '501 patent. These accused devices include the Daig ventricular silicone tined lead (PX 56), the Daig atrial J silicone tined lead (PX 58), the Daig urethane tined wedge lead (PX 60), and the Daig urethane atrial J tined lead (PX 62). The Daig ventricular silicone tined lead (PX 56) is an endocardial lead which has a plurality (4) of nonconducting barbs or projections or tine means located near the electrode tip. The tine means extend from the lead body and away from the electrode tip forming an acute angle with the lead body. The tine means could only be intended to cooperate with heart tissue to hold the electrode tip in position. The tine means are made of a material, silicone rubber, inert to body fluids, which is sufficiently rigid to maintain the acute angle of the tine means in relation to the lead body when unrestrained, yet sufficiently pliant to prevent penetration or perforation of heart tissue. The Court finds that Claim 1 of the '501 patent clearly reads on the accused Daig ventricular silicone tined lead. The Daig ventricular silicone tined lead literally infringes Claim 1 of the '501 patent.

Daig contends, however, that the ventricular silicone tined lead does not infringe Claim 1 of the '501 patent.

Daig makes the point that its tined lead does not have tine means *per se*, which are sufficiently rigid and pliant because of the physical properties of the material from which they are made, but rather has fins which are sufficiently rigid and pliant because of the structure of the fins. Daig also makes the point that its tined lead does not operate in the same manner as Claim 1 because, rather than moving up or down, towards or away from the lead body, its fins wrap around the lead body. The Court has considered Daig's points and finds them, to some extent, to be makeweight. The Court believes that the tines or fins of the Daig ventricular silicone tined lead are sufficiently rigid and pliant because of the material from which they are made, and operate in the same manner as the tines described in Claim 1. The Court remains convinced that the Daig ventricular silicone tined lead literally infringes Claim 1 of the '501 patent. To the extent, however, that Daig's points may not be makeweight and may serve to defeat literal infringement, the Court finds that this Daig endocardial lead performs substantially the same function in substantially the same way to obtain the same result as the Claim 1 device, and, therefore, infringes Claim 1 under the doctrine of equivalents.

The Daig urethane tined wedge lead (PX 60) is an endocardial lead which has a plurality (3) of nonconducting tine means located near the electrode tip. The tine means extend from the lead body and away from the electrode tip forming an acute angle with the lead body. The tine means are intended to cooperate with heart tissue to hold the electrode tip in position. The tine means are made of a material, urethane, inert to body fluids, which is sufficiently rigid to maintain the acute angle of the tine means in rela-

tion to the lead body when unrestrained, yet sufficiently pliant to prevent penetration or perforation of heart tissue. The Court finds that Claim 1 of the '501 patent clearly reads on the accused Daig urethane tined wedge lead. The Daig urethane tined wedge lead literally infringes Claim 1 of the '501 patent.

Daig argues, however, that the urethane tined wedge lead does not infringe Claim 1 of the '501 patent because the tines are an integral part of the wedge tip, not the lead body, and extend from the wedge tip, not the lead body. The Court has considered Daig's arguments and finds that the wedge tip is part of the encasing material of the lead body and that the tines extend from the lead body in the manner described in Claim 1. The urethane tined wedge lead, over Daig's arguments, literally infringes Claim 1 of the '501 patent. If, however, the wedge tip were not considered to be part of the encasing material of the lead body so as to defeat literal infringement, the Court would still find that the Daig urethane tined wedge lead infringes Claim 1 of the '501 patent under the doctrine of equivalents because it performs substantially the same function in substantially the same way to obtain the same result as the Claim 1 device.

The Daig atrial J silicone tined lead (PX 58) and urethane atrial J tined lead (PX 62) are endocardial leads which have a plurality (3) of nonconducting tine means located adjacent or near the electrode tip. The tine means extend from the lead body and away from the electrode tip forming an acute angle with the lead body. The tine means are intended to cooperate with heart tissue to hold the electrode tip in position. The tine means are made of a material, silicone rubber or urethane, inert to body fluids, which is

sufficiently rigid to maintain the acute angle of the tine means in relation to the lead body when unrestrained, yet sufficiently pliant to prevent penetration or perforation of heart tissue. The Court finds that Claim 1 of the '501 patent clearly reads on the accused Daig atrial J silicone tined lead and urethane atrial J tined lead. The atrial J silicone tined lead and urethane atrial J tined lead literally infringe Claim 1 of the '501 patent. Even if the Court could not find that the Daig atrial J silicone tined lead and urethane atrial J tined lead literally infringe Claim 1, the Court would find that these Daig devices infringe Claim 1 under the doctrine of equivalents because they clearly perform substantially the same function in substantially the same way to obtain the same result as the Claim 1 device.

The Court is satisfied that Medtronic has carried its burden of showing by a preponderance of the evidence that the accused Daig devices infringe Claim 1 of the '501 patent. The accused Daig devices, which include the Daig ventricular silicone tined lead (PX 56), the Daig atrial J silicone tined lead (PX 58), the Daig urethane tined wedge lead (PX 60), and the Daig urethane atrial J tined lead (PX 62), each literally infringe Claim 1 of the '501 patent. Even if the accused Daig leads did not literally infringe, the devices would infringe Claim 1 under the doctrine of equivalents because the devices perform substantially the same function in substantially the same way to obtain the same result as the Claim 1 device.

Pacesetter Tined Endocardial Leads

Medtronic offered eight Pacesetter tined endocardial leads as accused devices falling clearly within Claim 1 of the '501 patent. The accused devices include Pacesetter

Models 817 (PX 111), 819 (PX 113), 829 (PX 115), 833 (PX 117), 851 (PX 119), 853 (PX 121), 865 (PX 123) and 869 (PX 125). Pacesetter stipulated that if these accused devices were found to infringe Claim 1, then certain other related devices which Pacesetter sold would also infringe Claim 1. Consequently, if Pacesetter Model 817 is found to infringe, then Models 818 and 818A infringe; if Model 819 is found to infringe, then Models 820 and 825 infringe; if Model 833 is found to infringe, then Model 841 infringes; and if Model 865 is found to infringe, then Models 866 and 867 infringe, as well.

Pacesetter also stipulated that the testimony of William McArthur, the current Director of Leads Products for Pacesetter, with respect to Model 817 would be the same with respect to all other Pacesetter tined endocardial leads in evidence. McArthur stated that Model 817, which Pacesetter purchased from Diag, is an endocardial lead having an electrical conductor, which is encased in a material inert to body fluids, termining at an exposed electrically conductive electrode tip. McArthur also stated that Model 817 has nonconducting tine means which extend from the encasing material of the lead body and away from the electrode tip forming an acute angle with the encasing material. The tine means of Model 817 positioned relative to the electrode tip, McArthur admits, will cooperate with heart tissue to hold the electrode tip in position. The tine means of Model 817, McArthur further admitted, are made of a pliant material inert to body fluids which has sufficient rigidity to maintain an acute angle when the tine means are unrestrained, but sufficient pliancy to prevent penetration of heart tissue. McArthur, however, would not readily admit that the tine means of Model 817, or any other Pace-

setter tined endocardial lead, were adjacent to the electrode tip. While he would say that the tine means were close to the tip, he would not say that the tine means were adjacent to the tip.

McArthur's reluctance to admit that the tine means of Model 817 were adjacent to the electrode tip was perhaps an attempt to prevent Claim 1 from reading on Model 817 The Court, however, believes that McArthur's position with respect to tine means adjacent to the electrode tip amounts to semantic quibbling. Reading Claim 1 of the '501 patent in ordinary and reasonable manner, and looking at Model 817, the Court finds that not only are the tine means of Model 817 close to and near the electrode tip, but the tine means of Model 817 are also adjacent to the electrode tip.

The Court has carefully examined the testimony and exhibits relating to the Pacesetter tined endocardial leads, including Models 817, 819, 829, 833, 851, 853, 865, and 869. These Pacesetter devices are endocardial leads which have nonconducting tine means located adjacent or close to the electrode tip. The tine means of these devices extend from the lead body and away from the electrode tip forming an acute angle with the lead body. The tine means are intended to cooperate with heart tissue to hold the electrode tip in position. The tine means are made of a material inert to body fluids which is sufficiently rigid to maintain the acute angle of the tine means in relation to the lead body when unrestrained, yet sufficiently pliant to prevent penetration or perforation of heart tissue. The Court finds that Claim 1 of the '501 patent clearly reads on the accused Pacesetter devices, Models 817, 819, 829, 833, 851, 853, 865, and 869. Pacesetter Models 817, 819, 829, 833, 851, 853, 865, and 869 literally infringe Claim 1 of the '501

patent. Having found these Pacesetter devices to have infringed, in accordance with Pacesetter's stipulation, the Court finds that Pacesetter Models 818, 818A, 820, 825, 841, 866 and 867 also literally infringe Claim 1 of the '501 patent. Even if the Court could not find that the Pacesetter tined endocardial leads literally infringe Claim 1, the Court would find that the Pacesetter devices infringe Claim 1 under the doctrine of equivalents because they clearly perform substantially the same function in substantially the same way to obtain the same result as the Claim 1 device.

The Court is satisfied that Medtronic has carried its burden of showing by a preponderance of the evidence that the accused Pacesetter devices infringe Claim 1 of the '501 patent. The accused devices, which include, by offer at trial and stipulation, Pacesetter Models 817, 818, 818A, 819 820, 825, 829, 833, 851, 853, 865, 866, 867, and 869, each literally infringe Claim 1 of the '501 patent. Even if the accused Pacesetter did not literally infringe, the devices, because they perform substantially the same function in substantially the same way to obtain the same result as the Claim 1 device, would infringe under the doctrine of equivalents.

CONCLUSION

The Court has given its careful and detailed attention to the witnesses and evidence presented, and the numerous legal issues raised in this action. The Court remains unpersuaded that Claim 1 of the '501 patent was anticipated under § 102, that the invention disclosed in the '501 patent was obvious under § 103, and that specification of the '501 patent does not enable or set forth the best mode, or that Claim 1 of the '501 patent lacks definiteness under § 112.

Daig and Pacesetter have failed to persuade the Court of the invalidity of the '501 patent by clear and convincing evidence. The Court, therefore, continues to accept the '501 patent as valid.

The Court, however, is persuaded that Claim 1 of the '501 patent was infringed literally, and, in the alternative, under the doctrine of equivalents. The Court is satisfied that the accused Daig devices, which include the Daig ventricular silicone tined lead, the Daig atrial J silicone tined lead, the Daig urethane tined wedge lead, and the Daig urethane atrial J tined lead, and the accused Pacesetter devices, which include Models 817, 818, 818A, 819, 820 825, 829, 833, 851, 853, 865, 866, 867, and 869, infringe Claim 1 of the '501 patent. Medtronic has persuaded the Court by a preponderance of the evidence that the accused Daig and Pacesetter devices infringe Claim 1 of the '501 patent.

ORDER

IT IS ORDERED, ADJUDGED AND DECREED:

1. Medtronic, Inc. and Medtronic Puerto Rico, Inc. are, by assignment, the sole and lawful owners of United States Patent No. 3,902,501.

2. United States Patent No. 3,902,501 is valid and enforceable against Daig Corporation and Pacesetter Systems, Inc., now Siemens-Pacesetter, Inc.

3. The manufacture, distribution, sale, and use by Daig Corporation of its accused devices, the ventricular silicone tined lead, the atrial J silicone tined lead, the urethane tined wedge lead, and the urethane atrial J tined lead,

have infringed Claim 1 of the United States Patent No. 3,902,501 in violation of 35 U.S.C. § 271(a).

4. The manufacture, distribution, sale, and use by Pacesetter Systems, Inc., now Siemens-Pacesetter, Inc., of its accused devices, Models 817, 818, 818A, 819, 820, 825, 829, 833, 851, 853, 865, 866, 867, and 869, have infringed Claim 1 of United States Patent No. 3,902,501 in violation of 35 U.S.C. § 271(a).

5. The manufacture, distribution, sale, and use by Daig Corporation, its officers, directors, employees, agents, and all others acting in concert with it or through them, of the ventricular silicone tined lead, the atrial J silicone tined lead, the urethane tined wedge lead, the urethane atrial J tined lead, and any other tined endocardial lead embodying the elements of Claim 1 of United States Patent No. 3,902,-501 are permanently enjoined.

6. The manufacture, distribution, sale, and use by Pacesetter Systems, Inc., now Siemens-Pacesetter, Inc., its officers, directors, employees, agents, and all others acting in concert with it or through them, of Models 817, 818, 818A, 819, 820, 825, 829, 833, 851, 853, 865, 866, 867, 869, and any other tined endocardial lead embodying the elements of Claim 1 of United States Patent No. 3,902,501 are permanently enjoined.

Dated: June 24, 1985.

/s/ EARL R. LARSON
United States Senior District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
FOURTH DIVISION
Civil No. 4-79-256

Medtronic, Inc., Medtronic Puerto Rico, Inc.,

Plaintiffs,

v.

Daig Corporation,

Defendant.

and

Daig Corporation,

Plaintiff,

v.

Medtronic, Inc.,

Defendant.

MEMORANDUM ORDER

Robert T. Edell, Esq. and Albert L. Underhill, Esq. appeared on behalf of the plaintiffs, Medtronic, Inc., and Medtronic Puerto Rico, Inc. Joseph Bremayer, Esq. appeared of counsel.

Malcolm L. Moore, Esq. appeared on behalf of defendant, Daig Corporationg.

A hearing was held before the Court upon the motion of plaintiffs, Medtronic, Inc. and Medtronic Puerto Rico, Inc., for an order preliminarily enjoining defendant, Daig Cor-

poration, from any further manufacture, use or sale of any pacemaker leads which infringe upon Claim 1 of Medtronic's United States Letters Patent Citron et al. 3,902,501 including but not limited to the following Daig tined leads:

Daig's ventricular tined lead, (PX 56);
Daig's atrial J silicone tined lead, (PX 58);
Daig's urethane tined wedge lead, (PX 60); and
Daig's atrial J urethane tined lead, (PX 62).

Medtronic commenced this action on May 29, 1979. Daig responded to Medtronic's complaint by denying infringement in its answer and counterclaiming for a declaration of invalidity of the patent-in-suit and asserting certain antitrust counterclaims. In December of 1980, Daig filed Civil Action No. 4-80-611 against Medtronic, Inc. for infringement of United States Letters Patent 4,236,529 which action was consolidated for trial and discovery with Civil Action No. 4-79-256. On June 10, 1981, a Petition in Involuntary Bankruptcy was filed against Daig. The involuntary petition was converted to a Chapter 11 proceeding, and this case was stayed pursuant to the automatic stay provisions of the Bankruptcy Code. After trial before the Bankruptcy Court on March 9, 1982, the Bankruptcy Court entered an order on April 15, 1982, permitting Medtronic to pursue only its claim for injunctive relief in this Court. In May of 1982, Medtronic moved this Court for an expedited trial date which was denied by order of this Court dated August 12, 1982. On October 12, 1982, Medtronic filed a motion for a preliminary injunction requesting that Daig be enjoined pending trial on the merits from any further infringement causing Medtronic continuing irreparable harm. Origi-

nally, the hearing on Medtronic's motion for a preliminary injunction was set for December 12-14, 1982. Upon Daig's request, the hearing was rescheduled to commence January 10, 1983. Subsequently, on November 16, 1982, Daig filed a motion to stay the subject litigation as to the Medtronic '501 Patent pending a determination as to the validity of that patent in Medtronic's suit against Intermedics, Inc. which is pending in the United States District Court for the Southern District of Texas, Galveston Division. By Order of December 22, 1982, this Court confirmed the January 10, 1983 hearing date on Medtronic's motion for a preliminary injunction and denied Daig's motion to stay. An extensive two-week hearing ensued.

This Court has jurisdiction under the provisions of Title 28, United States Code § 1338(a).

The following memorandum constitutes the Court's findings of fact and conclusions of law required by Federal Rule of Civil Procedure 52(a).

Upon motion for preliminary injunctive relief, the Court must consider:

1. the threat of irreparable harm to the movant;
2. the state of balance between this harm and the injury that granting the injunction will inflict on other parties litigant;
3. the probability that movant will succeed on the merits; and
4. the public interest.

Dataphase Systems, Inc. v. C. Systems, Inc., 640 F.2d 109 (8th Cir. 1981). Since this is a motion for a preliminary

injunction by a patentee, the law further requires that Medtronic "show beyond question" that the Citron '501 Patent is valid and infringed and that Medtronic holds title to the '501 Patent. *Rohm & Haas Co. v. Mobil Oil Corp.*, 525 F. Supp. 1298, 1303 (D. Del. 1981). Generally the validity of a patent is established beyond question (1) where the patent has been the subject of long-standing public acquiescence in which other members of the industry have failed to contest its validity or to infringe the patent; (2) the patent has previously been adjudicated valid on relevant grounds; or (3) the patent is supported by clear and convincing evidence of technical validity. *Id.* at 1303.

Plaintiffs, Medtronic, Inc. and Medtronic Puerto Rico, Inc. (Medtronic) are Minnesota corporations. Medtronic is the owner by assignment of United States Letters Patent Citron et al. 3,902,501 (the '501 Patent). Twenty percent of the '501 Patent has been assigned to Medtronic Puerto Rico, Inc. which is a wholly owned subsidiary of Medtronic, Inc. engaged in the manufacture of Medtronic cardiac pacemaker leads, including the Medtronic tined leads. The '501 Patent, entitled "Endocardial Electrode", issued on September 2, 1975 in the name of Paul Citron and Eugene A. Dickhudt on an application filed June 21, 1973. Medtronic has charged defendant Daig Corporation with infringment of Claim 1 of the '501 Patent which embraces a tined endocardial pacemaker lead. Medtronic further alleges in its motion for a preliminary injunction that Daig's continued sale of infringing leads while under the protective umbrella of the bankruptcy stay is causing Medtronic irreparable harm pendente lite.

Defendant Daig Corporation is also a Minnesota corporation engaged in the manufacture and sale of cardiac

pacemaker leads. Daig denies that it has infringed Claim 1 of the '501 lead and contends that Medtronic has failed to meet the requisite burden for the granting of a preliminary injunction on a number of grounds. Daig asserts that the technical evidence before the Court not only fails to establish the validity of the '501 Patent beyond question; but it demonstrates a strong likelihood that in a trial on the merits, Claim 1 of the '501 Patent will be found invalid due to 1) lack of novelty, 2) obviousness in light of the prior art, 3) indefiniteness, 4) as being based on new matter, and 5) for fraud on the patent office. Daig argues that the prior adjudication upon which Medtronic relies also fails to establish validity beyond question because the adjudication in which Medtronic was granted a German Utility Patent on its tined leads did not involve the same standards for invention as are applied in the United States to regular patents. Daig also argues that Medtronic is not being irreparably harmed and that the balance of hardships and public interest favor Daig.

Background of the '501 Patent

A pacemaker is a device comprised of a pulse generator, a lead and a power source which is used to provide electrical stimulation to the heart in order to restore an acceptable heart rate in a patient whose heart rate is too low or erratic. The pulse generator determines the rate and amplitude of the electrical pulses which are conducted through a lead to the heart. Both the pulse generator and the lead are implanted within the body. It is imperative that both the pulse generator and the leads be highly reliable in order to survive in the human body which is an extremely hostile environment to foreign bodies.

The first leads or electrodes used in cardiac pacemakers, such as Medtronic Model 5815, were sewn or sutured to the outside of the heart either against the epicardium or into the myocardium. The myocardium of the heart is the muscle of the heart which lies between the epicardium (the thin fibrous lining covering the outside of the heart) and the endocardium (the thin fibrous inner lining).

Implantation of the early myocardial or epicardial leads required a major surgical procedure called a thoracotomy in order to obtain direct access to the heart. It was a traumatic experience for the patient requiring general anesthesia and retraction to expose the heart. Subsequent developments in myocardial leads, such as the Medtronic Model 6917 screw-in lead, required a less traumatic surgical procedure for implantation called a tunneling technique. However, this procedure was still generally regarded as major surgery requiring general anesthesia in most instances.

Endocardial leads were developed in an attempt to reduce trauma in implantation. Endocardial leads are implanted by means of a transvenous procedure requiring a local anesthetic and a small incision. An incision is made in the vein and the lead is inserted through the vein into the inside of the heart and positioned in contact with the endocardium.

The earliest endocardial leads were straight-shanked with no means, active or passive, to hold the lead electrode in contact with the heart wall. Rather, they were wedged between heart tissue in the ventricular apex. High dislodgement rates with consequent loss of pacing capability and frequent need for reoperation made physicians reluctant to use these early endocardial leads.

Endocardial leads with flange tips, Model Nos. 6901 and 6907, were designed, manufactured and marketed by Medtronic by 1970. The flange tip is a conical shape made of silicone rubber designed to wedge in the trabeculae of the right ventricle to hold the electrode in place in much the same manner as the straight-shanked leads. The trabeculae are ridges or bands of muscle most prominent in the ventricular apex and atrial appendage. Medtronic was never able to prove statistically that the wedge or flanged lead enjoyed lower dislodgement rates that the straight-shanked leads.

Various configurations for the tips of the endocardial leads were developed in an attempt to improve lead stability. Certain configurations such as the corkscrew and barb have active fixation means. Active fixation leads require the use of a mechanism manipulated by the physician from outside the body to impale, grasp, squeeze or bite the myocardium resulting in some amount of direct trauma to the myocardium.

Development of the '501 Patent

In February of 1972, Mr. Paul Citron was hired by Medtronic and assigned the task, along with Mr. Eugene Dickhudt, of developing an atrial pacing system. At the time, the majority of pacemakers were used in the ventricle or lower chambers of the heart. In preparation for this assignment, Mr. Citron looked at the anatomy and read the literature on available atrial pacing systems in order to become familiar with the experiences of others and to assess the reported results. Mr. Citron did not directly research the ventricle pacing systems then available.

Several epicardial leads and several J-shaped endocardial leads had been used for atrial pacing. Barbed or hooking leads by Biotronic were another transvenously applied lead system which had been used for atrial pacing. In addition, conventional transvenous ventricular leads had been used for placement in the coronary sinus which is a blood vessel opening in the right atrium.

There were two components to the task of Citron and Dickhudt in developing an atrial pacing system. The first component was the pacemaker portion, i.e. the stimulation and sensing portion. The second component of the problem was the lead, i.e. how to deliver the stimulation to the desired parts of the heart. Mr. Citron testified that the absence of a viable, reliable atrial lead system was regarded as the main barrier in developing an atrial pacing system.

Citron and Dickhudt attempted a number of lead designs which were recorded in a laboratory notebook, (PX 42). One of the designs envisioned applying a lead with glue; another design envisioned a lead with hooks or barbs to fix the lead to the myocardium of the atrium, another design envisioned the use of a vacuum to assist in placing the lead. The first embodiment of the Citron-Dickhudt tined endocardial lead embraced by Claim 1 of the '501 Patent is disclosed in the laboratory notebook at page 50, dated July 7, 1972.

In Mr. Citron's opinion, Claim 1 of the '501 Patent incorporates a transvenous lead with a number of soft, pliant non-tissue damaging tines to effect passive fixation in the heart to stimulate the heart. (Passive fixation requires no remote manipulation of a grasping or penetrating mechanisum to effect fixation).

Mr. Citron testified that no literature at the time that he and Mr. Dickhudt commenced developing an atrial pacing system showed this type of lead. Mr. Citron further testified that in July of 1972, he was familiar with dislodgement problems with existing ventricular and atrial leads. However, it was not apparent to Citron and Dickhudt in July of 1972 that the tined lead would work or would improve dislodgement because animal testing often showed that prototypes did not work well.

Prior to a lead being marketed by Medtronic, the following tests generally take place. There is limited bench testing in which the electrical mechanical aspect of a lead is tested. Then animal testing is conducted in which an attempt is made to combine the engineering and physiology in order to get the two to work together practically. Surgery is performed on animals and an attempt is made to use the lead as it is thought it should be used. Acute and chronic testing follows. Acute tests are those conducted for a short period of time. Chronic tests are long term tests lasting for days, weeks or months during which frequent observation of the hardware and heart occur.

During the period of time from July 7, 1972 through December 22, 1975, the tined lead developed by Citron and Dickhudt was tested both in animals and in humans. In 1975, Mr. Citron authored a research report on the performance of the atrial tined endocardial J-lead in approximately 40 humans. The studies on implantation of this lead in humans were conducted by Dr. Nicholas Smyth, a consultant retained by Medtronic who has expertise in atrial pacing. The results of the testing in humans were favorable. (See PX 43).

Upon completion of the research on the tined lead in December of 1975, it went into product development. The research and development expense of the tined lead, excluding marketing expenses, was at least $500,000.

In 1976, Medtronic began marketing the tined lead. Medtronic first incorporated the Citron tined endocardial lead into its product line in models 6950 and 6951 tined ventricular leads and models 6990 and 6991 tined atrial leads. Subsequently, Medtronic has introduced additional ventricular tined leads models 6961, 6962, 6971, 6972 and atrial tined models 6690U (urethane) and 6991U (urethane). The parties dispute whether these later models with shorter stubby tines have incorporated the Citron tined endocardial lead embodied in Claim 1 of the '501 Patent.

When the tined endocardial lead was first marketed by Medtronic, Mr. Lawrence W. Shearon, Vice-President of Clinical Research on Medtronic, testified that many concerns were expressed by physicians. Subsequently, the cardiac pacemaking industry and medical community have recognized that the tined lead has resulted in significantly reduced dislodgement rates and reduced incidence of complications requiring reoperation. (*See* PX 33, 48, 49, 50, 51, 52 and 65). Dr. James P. Maloney, a cardiologist with the Mayo Clinic, testified that the tined lead is now considered the lead of choice by a majority of cardiologists.

Validity of the '501 Patent

Claim 1 of United States Patent Citron et al. 3,902,501 is as follows:

> In an endocardial lead of the type having an electrical conductor

encased in a material which is generally inert to body fluids,
the conductor terminating at an exposed electrically conductive electrode tip, the improvement which comprises:
nonconducting tine means
extending from said encasing material and away from said tip
for cooperating with heart tissue, to hold the tip in position,
said tine means forming a generally acute angle with said encasing material
and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained,
but sufficiently pliant to prevent penetration of said heart tissue,
said pliant material being generally inert to body fluids.

A threshold issue before the Court is the scope and meaning of Claim 1 of the '501 Patent. Mr. Donald W. Banner, former U.S. Commissioner of Patents and Trademarks, testifying on behalf of plaintiffs, found support and correspondence of the elements of Claim 1 in the structure disclosed and described in the '501 Patent, particularly Figure 1. Mr. Richard O. Bartz, a former Assistant Patent Examiner, testifying on behalf of defendant, was of the opinion that Claim 1 of the '501 Patent was invalid for indefiniteness under 35 U.S.C. § 112. Specifically, Mr. Bartz was of the opinion that the language "but sufficiently pliant to prevent penetration of said heart tissue" finds no clear antecedent basis and support in the original specifica-

tion of the '501 Patent application. This language was added to Claim 1 by the Patent Examiner with the stated purpose of rendering Claim 1 complete and definite under § 112. (*See* '501 file wrapper, PX 2, p. 50). Mr. Bartz also was of the opinion that the language "to hold the tip in position" is indefinite in that it is hanging. This language was added to Claim 1 by amendment. (*See* '501 file wrapper, PX 2, p. 26).

35 U.S.C. § 112 reads in pertinent part:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

One of the main purposes of § 112 is to require patentees to define their inventions with sufficient particularity that would-be-infringers know the perimeter of the legal protection to which the patentee is entitled. *Palmer v. United States,* 423 F.2d 316, 319 (Ct. Cl. 1970), *cert. denied,* 400 U.S. 950 (1970). The precise wording of a patent claim need not be found in the patent specification as long as the claim language is clear when read in light of the disclosure of the specification as a whole. *Application of Smith,* 481 F.2d 910, 914 (C.C.P.A. 1973).

Although the terms "pliant" and "without penetration" are not expressly defined in the patent specification, the Court finds the terms clear when read in light of the disclosure of the specification as a whole. The tines of the '501 Patent are described in the specification as "of a pliant material which is sufficiently rigid to accomplish their purpose without having the snapping action and sharp points

attendant in the prior art devices." ('501 Patent, PX 1, column 6, lines 24-28; '501 file wrapper, PX 2, page 15, lines 13-15). The preferred materials for the tines are stated to be silicone, rubber and polyurethane. (PX 1, Column 3; lines 6-7; PX 2, page 9, lines 3-5.) This is preceded by a description of prior art devices, in which it is stated that "the metallic nature of the hooks, their sharp points and spring action create the possibility that the hooks may perforate the wall of the appendage if the catheter tip is not precisely positioned." (PX 1, column 2, lines 3-6; PX 2, page 7, lines 1-4.) Upon cross-examination, Mr. Bartz agreed that the snap action of the sharp points of prior art devices is what created perforation. The Court finds the original patent specification of the '501 Patent clearly supports the claim language that the tine means are "sufficiently pliant to prevent penetration of said heart tissue".

In addition, the Court finds no merit to the argument that the claim language "to hold the tip in position" is indefinite under § 112. It is obvious from the specification that the electrode tip must be held in electrical contact with heart tissue. The specification describing Figure 1 in the '501 Patent states that the purpose of the tines is "to cooperate with the body tissue, particularly the trabeculae of the right atrial appendage, to maintain the tip 11 in electrical contact with the body tissue." (PX 1, column 3, lines 16-19; PX 2, page 9, lines 13-15).

Defendants also contend that the claim language "sufficiently pliant to prevent penetration of said heart tissue" comprises new matter added to the specification which renders the claim invalid under 35 U.S.C. § 132. Title 35 U.S.C. § 132 prohibits introducing new matter by way of

amendment into the disclosure of the invention. However, the above-quoted language was not added to the specification of the patent application, but rather to Claim 1 of the application. Additions to claims are to be reviewed under § 112. *In Re Rasmussen,* 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). The Court has already found that this language meets the requirements of § 112.

The Court finds that the elements of Claim 1 of the '501 Patent find support and correspondence in the structure disclosed and described in the '501 Patent.

The final issue posed by the parties as to the scope and meaning of Claim 1 of the '501 Patent is whether the tines embraced by this claim are limited to the longer projections depicted in the patent drawings or whether the tines also embrace the shorter stubby tines found in later models produced by Medtronic. *See* the Court's discussion of this issue *infra.*

In order to be patentable, an invention must meet the statutory standards of 35 U.S.C. §§ 101, 102 and 103 which require:

(1) utility
(2) novelty, and
(3) the subject matter sought to be patented to a person having ordinary skill in the pertinent art.

Graham v. John Deere Co., 383 U.S. 1, 12 (1966). An issued United States Patent is presumed valid under 35 U.S.C. § 282. However, this presumption of validity will not support the granting of a preliminary injunction in a patent case. *Mayview v. Rodstein,* 480 F.2d 714, 718 (9th Cir. 1973). As previously stated, a patentee seeking a preliminary injunction must prove "beyond question" that the

patent in issue is valid. *Rohm & Haas Co. v. Mobil Oil Corp.*, 525 F. Supp. at 1303. This burden may be met by demonstrating that that patent at issue has been the subject of long acquiescence; that patent at issue has been previously adjudicated valid on relevant grounds; or that the patent at issue is supported by clear and convincing technical evidence. *Id.*

Clear and Convincing Technical Evidence

(1) Utility

There is no dispute that the Citron endocardial tined lead has utility, and the Court finds that the evidence amply demonstrates its utility. Dr. Maloney testified that he presently uses tined leads in ninety to ninety-five percent of his cases. Dr. Maloney estimated that the tined lead is probably used in ninety percent of transvenous pacing implants. In addition, the evidence establishes that the endocardial tined lead has significantly reduced dislodgement rates. (*See* PX 33, 48, 49, 50, 51, and 65).

(2) Novelty

The novelty requirements for patentability are set forth in 35 U.S.C. & 102. Daig contends that sections 102(a), 102(b) and 102(g) bar patentability of Claim 1 of the '501 Patent which read in pertinent part:

> A person shall be entitled to a patent unless —
>
> (a) the invention was known or used by others in this country . . . before the invention thereof by the applicant for patent or
>
> (b) the invention was . . . described in a printed publication in this or a foreign country . . . more

than one year prior to the date of the application for patent in the United States, or

* * * *

(g) before the applicant's invention thereof, the invention was made in this country by another who had not abandoned, suppressed or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Daig relies upon the Spickler-Rasor article entitled "Totally Self-Contained Intracardiac Pacemaker" published in the *Journal of Electrocardiology,* 1970 (PX 22) to show lack of novelty in the subject mater of Claim 1 of the '501 Patent under 35 U.S.C. § 102(b).

There are three basic teachings in the Spickler et al. article: (1) a totally encapsulated pacemaker without a lead means; (2) a means of fixation for encapsulated pacemakers or transvenous leads; and (3) beta cells. The article recognizes that "two major problems with conventional pacemakers are perforation or dislocation of the transvenous electrode and the short life of the batteries that are presently used." (PX 22, p. 325). The main teaching of the article is to be able to place the entire pacemaker in the heart. One objective in doing so would be to eliminate dislodgement and fracturing probabilities of leads.

Under the section subtitled "Prototype Development" on page 327 of the article, it discusses problems en-

countered in designing the attachment mechanism for the intracardiac capsule. The article states that Figure 2 "shows some of the early designs [of attachment techniques] that were tried and ruled out." (PX 22, p. 327). The devices depicted in Figure 2 are described as follows:

> The original plan employed a fish-hook type barb which would be pressed into the myocardium. This technique was not satisfactory, *so the method of using several radiating fingers which would catch in the traviculae of the ventricle was tested and rejected.* Later a method for screwing the pacemaker into the myocardium was developed, first using a corkscrew type attachment barb and then, finally, the presently-used, radially-directed spiral barbs. (PX 22, p. 327) (emphasis added).

The two middle photographs in Figure 2 depict the radiating finger concept. Figure 4 on page 328 depicts the present capsule design with radially-directed spiral attachment barbs. The description of Figure 5 indicates that the barbs imbed into the myocardium by active fixation; i.e. by screwing via remote manipulation. The photographs in Figure 2 and the above quoted statement in which the radiating fingers were tested and rejected as an attachment mechanism for the dummy capsules are the only references to the radiating finger concept in the article.

The article proceeds to discuss chronic studies which were performed using a device with the radially-directed spiral barbs for attachment that demonstrated a low stimulation threshold. Besides being of value for an intracardiac pacemaker, the article states that "the advantages of firm attachment and low threshold can be utilized with con-

ventional pacemakers in the form of an attached endocardial electrode." (PX 22, p. 327-328).

Daig contends that the Spickler et al. article in describing the radiating finger concept taken in context of the overall disclosure of the article in regard to conventional leads anticipated the Citron tined endocardial lead under § 102(b).

The parties have stipulated that the Spickler et al. article was published more than one year prior to the filing date of the Citron '501 Patent. Therefore, there is no dispute that the Spickler et al. article meets this qualification of § 102(b). In addition, there is no dispute that the Spickler et al. article was not before the Patent Examiner in the prosecution of the '501 Citron Patent.

As a rule, in order to have anticipation, all of the elements of the patented device or their equivalents must be found in a single prior art reference. *Palmer v. United States,* 423 F.2d at 321.

A prior publication anticipates so as to preclude novelty if it discloses all the elements of the claimed invention, or their equivalents, functioning in substantially the same way to produce substantially the same result, and if it teaches sufficient information to enable one skilled in the art to practice the invention. *The Garrett Corporation v. United States,* 422 F.2d 874, 878 (Ct. Cl. 1970), *Greening Nursery Company v. J and K Tool and Manufacturing Co.,* 376 F.2d 738, 740, 153 (U.S.P.Q. 660, 662 (8th Cir. 1967).

All of the disclosure of the reference must be considered for what it fairly teaches one of ordinary skill in the art. *In Re Boe,* 355 F.2d 961, 965 (C.C.P.A. 1966). It is proper to take into account not only specific teachings of the refer-

ence, but also the inferences which one skilled in the art would reasonably be expected to draw from the disclosure. *In Re Preda,* 401 F.2d 825, 826 (C.C.P.A. 1968).

Enablement exists if

> one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought. Unless this condition prevails, the description in the printed publication is inadequate as a statutory bar to patentability under § 102(b) . . . . *In Re Sasse,* 629 F.2d 675, 681 (C.C.P.A. 1980).

One skilled in the art must be able to devise the invention without further genuine inspiration or undue experimentation. *Struthers Scientific & International Corp. v. Rappl & Hoenig Co.,* 453 F.2d 250, 255 (2nd Cir. 1971).

An inoperable invention or one which fails to achieve its intended result does not negate novelty. *United States v. Adams, et al.,* 383 U.S. 39, 50 (1966). However, anticipation is not avoided by showing lack of prior success if all that remains to be done to make the device successful are changes involving the application of mere mechanical skill. *American Infra-Red Radiant Co., Inc. et al. v. Lampert Industries, Inc. et al.,* 149 U.S.P.Q. 722, 731 (8th Cir. 1966, *In Re Downie,* 368 F.2d 1014, 1015 (C.C.P.A. 1966).

Daig's expert witness, Mr. Harry Friedman, a biomedical engineer, who was qualified and knowledgeable in regard to pacing at the time of the Citron invention in 1972,

found correspondence of all of the elements of Claim 1 of the '501 Citron Patent in the article. In addition, Mr. Friedman testified that when he first saw the Spickler et al. article in 1970 while employed at Medtronic, at first glance he thought the devices in Figure 2 were depicting the end of a lead.

The Court finds that correspondence of the elements of Claim 1 of the '501 Patent or their equivalents cannot be found in the Spickler et al. article. Mr. Friedman admitted that the radiating finger devices in Figure 2 are not shown in conjunction with an endocardial lead. Rather, they are shown in conjunction with a dummy intracardiac capsule. The article does say that the test capsules were powered externally through transvenous leads. (PX 22, p. 327). However, the Court finds that the article never discusses at any point the use of the radiating finger devices as a possible attachment mechanism for conventional electrodes or leads. Much ado was made by various witnesses as to whether the language previously quoted from pages 327 and 328 which talked of the advantages of firm attachment being able to be utilized with conventional leads referred only to the radially-directed spiral barbs depicted in Figure 4 or also encompassed the radiating finger devices in Figure 2. The Court finds that the plain language of the article makes clear that this reference is made to the radially-directed spiral barbs and their fixation capacity. There is no discussion anywhere in the article as to how the radiating fingers in fact functioned. The article does say the radiating fingers were intended to catch in the trabeculae, but were tested and rejected.

Mr. Friedman also admitted that the article did not reveal the material of the radiating fingers. Rather, he

assumed that the material was some type of nylon because the fingers appear to be pinched off in a manner consistent with the properties of nylon. Mr. Friedman assumed that the fingers would not penetrate because obviously one would not want anything to penetrate in passing transvenously. However, Mr. Friedman also agreed that the article discussed an attachment mechanism which was made to actually hook into tissue. In addition, Mr. Friedman admitted that nylon could perforate if of the right derometer. In sum, the Court finds that the article does not disclose the essential features of the Citron tined endocardial lead. In particular it does not disclose an endocardial lead with pliant tines "sufficiently rigid to maintain an acute angle but sufficiently pliant to prevent penetration of the heart tissue."

The only testimony relating to the enabling aspect of the Spickler et al. article is that of Dr. James P. Maloney, a cardiologist with the Mayo Clinic who has had extensive experience implanting transvenous leads and who was knowledgeable and qualified in pacing in 1972. Dr. Maloney found that the article would not have made obvious to one skilled in the art in 1972 that the Citron tined endocardial lead would work. The Court finds that the Spickler et al. article would not have put one skilled in the art in 1972 in possession of an operable tined endocardial lead with the elements of Claim 1 of the '501 Patent or their equivalents by simply applying mechanical skill without undue experimentation. Accordingly, there is no basis for anticipation under 35 U.S.C. § 102(b).

While the plaintiffs may not rely upon the presumption of validity accorded to patents in proving the validity of the '501 Patent in this motion for a preliminary injunction, the

Court would note that although the Spickler et al. article was admittedly not before the Patent Examiner in the prosecution of the '501 Patent, no presumption of validity is defeated by this fact. Even if the depiction of the radiating finger concept in the article were deemed a concept closer to the Citron tined endocardial lead than any device considered by the Patent Examiner, it still does not teach the essential features of the Citron invention embraced by Claim 1 upon which patentability was predicated. Accordingly, it does not overcome the presumption of validity of the '501 Patent as defendant contends. *Palmer v.United States,* 423 F.2d at 322.

In addition, the Court finds no basis for anticipation under 35 U.S.C. § 102(a) based upon the radiating finger device of Spickler and Rasor being known or used by others in this country before the invention of Citron and Dickhud'.

In order for prior knowledge or use to negate novelty, the prior invention must be identical with or substantially similar to the invention under consideration. In addition, the prior invention must have been actually reduced to practice and in the public domain. *Deller's Walker on Patents,* § 78, Second Edition 1964. To prove a reduction to practice, it must be shown that the invention is suitable for its intended purpose. However, there is no requirement that the invention, when tested, be in a commercially satisfactory stage of development. *Randolph v. Shober,* 590 F.2d 923, 926 (C.C.P.A. 1979).

The evidence establishes that Dr. Ned Rasor presented a slide show to an Intersociety Energy Conversion Engineering Conference (IECEC) in September of 1970 at Las Vegas, Nevada. Rasor's presentation lasted about fifteen minutes during which Rasor described the technology relat-

ing to the intracardiac pacemaker project. One slide was shown which depicted the radiating finger concept. (DX 68). This slide corresponds to the middle left photograph which appears in Figure 2 of the Spickler et al. article (PX 22) and also corresponds to the device shown on page 6 of Rasor and Spickler's private laboratory notebook (DX 11).

The deposition testimony of Dr. Rasor establishes that his presentation of the radiating finger concept at the IECEC was very similar to the description in the Spickler et al. article and perhaps not as specific. (DX 22, pp. 60-61). In addition, the evidence establishes that Peter Mulier and Joel Hixon, employees of Medtronic, attended the IECEC presentation and among others, approached Dr. Rasor after his presentation. It was Dr. Rasor's recollection that he did expand upon the subject of stabilization of the electrodes with these individuals. (DX 22, p. 64). However, Dr. Rasor was not able to reconstruct the details of the conversation. (DX 22, p. 63). Drs. Rasor and Spickler also testified that they later met with Earl Bakken and Alan Kahn of Medtronic after the IECEC presentation. The record of the meeting shows that no materials were given to Mr. Bakken or Mr. Kahn. (DX 22R, p. 93, DX 24, pp. 88-89).

The Court has already determined that the Spickler et al. article does not disclose a device substantially similar to the Citron-Dickhudt tined endocardial lead embraced by Claim 1 of the '501 Patent or enable one skilled in the art to construct or be put in possession of the Citron-Dickhudt tined endocardial lead with only mechanical skill and no undue experimentation. By Dr. Rasor's own admission, his slide presentation at the IECEC added no information beyond that contained in the article. There is no evidence that during Dr. Rasor's discussions or meetings subsequent to

his slide presentation at the IECEC that additional pertinent information was imparted. The fact that the device shown in the slide corresponds to the device shown on page 6 of the Rasor-Spickler laboratory notebook does not add any evidence toward establishing prior public use or knowledge under § 102(a). The Rasor-Spickler laboratory notebook admittedly was maintained in secrecy, unwitnessed by a third party, and not published or shown to anyone other than co-workers. (DX 22, p. 69; DX 24, p. 90).

Daig also claims that prior inventorship by Drs. Rasor and Spickler negates novelty of the '501 Patent under 35 U.S.C. § 102(g). Daig contends that the Rasor-Spickler Laboratory Notebook, in particular page 7, establishes a prior actual reduction to practice of the radiating finger concept, and in the alternative that pages 6 and 7 of the notebook establish prior conception as of November 6, 1969 which was constructively reduced to practice with due diligence no later than September 21, 1970, the filing date of the United States Patent Rasor et al. 3,835,864 (PX 13). Daig contends that Figure 12 and columns 9 and 10 of the specifications of the Rasor '864 Patent disclose and describe the radiating finger concept for a lead. Daig relies solely upon the uncorroborated deposition testimony of Rasor and Spickler to supplement the disclosures of their unwitnessed laboratory notebook to establish conception and actual reduction to practice.

It is well-established that independent corroboration other than an inventor's own testimony and private records is required to establish prior conception and reduction to practice. *Mikus and Schaffer v. Wachtel,* 542 F.2d 1157, (C.C.P.A. 1976); *Lockheed Aircraft Corp. v. United States,* 553 F.2d 69, 74 (Ct. Cl. 1970). The testimony of joint inventors does not establish independent corroboration.

Anderson and Truett v. Pieper, Rickert, and Stein, 169 U.S.P.Q. 788, (C.C.P.A. 1971).

However, even considering the uncorroborated testimony of Rasor and Spickler, the Court does not find that the evidence establishes prior inventorship of the Cirton-Dickhudt tined endocardial lead under 35 U.S.C. § 102(g).

Pages 6 and 7 of the Spickler-Rasor notebook indicate that certain experiments were conducted using a radiating finger device. The device on page 6 was inserted by Dr. Spickler into an excised dog heart to determine size relationship on November 6, 1969. (DX 11, p. 6). The notebook reveals no more about this device. The deposition testimony of Dr. Spickler states that there was no determination that the radiating fingers could carry out the intended design function of attachment for a self-contained intracardiac pacemaker because the dog heart was not beating. (DX 24, p. 30). It was determined that the fingers could engage the trabeculae, but there was no determination as to whether there was adequate attachment (DX 24, p. 30).

The device on page 7 of the notebook was inserted transvenously into the right ventricle of a live dog on November 13, 1969. The notebook states that it was possible to capture the right ventricle, but the external wire broke as a result of manipulation. After the wires broke, Dr. Spickler testified that they did not carry the test any further. Dr. Spickler stated that he thought the test noted on page 7 implied there was adequate attachment. (DX 24, p. 31). This device is not shown in the Spickler et al. article or in the slide shown to the IECEC. There is no evidence of public accessibility to the device on page 7.

Dr. Spickler testified that he thought they were probably attempting to develop fingers which would not penetrate any

portion of the heart. (DX 24, pp. 28-29). Dr. Spickler was not certain as to the nature of the material comprising the fingers. (DX 24, p. 66). Both he and Dr. Rasor thought the material was a surgical suture material and probably nylon. (DX 24, p. 29; DX 22, p. 34). Dr. Spickler stated that there was no way of knowing from the tests whether the radiating fingers penetrated the heart tissue or not. (DX 24, p. 30). In sum, even the deposition testimony of Drs. Spickler and Rasor contains a great deal of supposition as to their conception of the radiating finger devices depicted on pages 6 and 7. The Court does not find that the photographs on pages 6 and 7 show a complete conception, free from ambiguity or doubt, which include the essential features of the Citron tined lead. *Gould v. Schawlow*, 363 F.2d 908, 916 (C.C.P.A. 1966).

Furthermore, even if Drs. Rasor and Spickler could be credited with prior conception of the '501 tined lead, the evidence falls far short of establishing an actual reduction to practice of a device substantially similar to the '501 tined lead.

Even Daig's witness, Mr. Bartz, testified that from the laboratory notebook and the deposition testimony of Drs. Rasor and Spickler, he was unable to determine the specific date that there was a successful reduction to practice. Furthermore, Mr. Bartz was unable to state from the evidence whether there ever had been a successful actual reduction to practice.

Dr. Spickler testified that subsequent to the publication of the Spickler et al. article in 1970, none of the attachment mechanisms (Figure 2, PX 22) which the article states as being tested and rejected were utilized or tested for viability for any purpose. (DX 24, p. 82). After the publication of the

Spickler et al. article, Drs. Rasor and Spickler never used the radiating finger device in any of their research and development work on attached electrodes, i.e. leads with attached electrodes. (DX 24, pp. 80-82). In a document prepared by Rasor Associates sometime between 1976 and 1980 entitled "Low Threshold Attached Electrode", (PX 91), which specifically discusses their lead development work, the Spickler et al. article is attached as Appendix A with the notation "For key elements of attached electrode development use pp. 327-329." As discussed *supra,* these pages summarily state that the radiating finger concept was tested and rejected.

In Dr. Rasor's deposition testimony regarding plaintiff's exhibit 91, Dr. Rasor asserts that the article (Appendix A) does not reject the radiating finger concept as an attachment mechanism for conventional leads, and yet he agreed that the article does not specifically state that the radiating fingers depicted in Figure 2 of the article formed firm attachment for any purpose. (DX 22 A, p. 60). The device being used at the time of the article was the device with the radially-directed spiral barbs. (DX 22 A, p. 60). The Court finds that the "Low Threshold Attached Electrode" (PX 91) which specifically addresses their lead development work, demonstrates that Rasor and Spickler, at least as late as 1976, had no confidence that they had previously invented a viable fixation mechanism utilizing the radiating fingers for use in conventional electrodes which was substantially similar to the '501 tined lead.

Nor is there any basis for finding a constructive reduction to practice of the '501 tined lead in the Rasor '864 Patent. Figure 12, which is the most pertinent disclosure within the '864 Patent, does not anticipate the '501 Patent. Figure

12 and columns 9 and 10 disclose an embodiment of a transvenous lead which has a pair of attachment wires 115 and 116 which are intended to "imbed" within the heart muscle to effect fixation. The description directs that "some pull could be placed on the lead 122 to complete attachment if necessary." (Column 10, lines 27-33). The pair of wires extend rearwardly and outwardly from the electrode tip 132. They are movable between a retracted position when within the protective insertion tool to a spread apart position when released for attachment. The wires are located at a position remote from the electrode tip 132, but are described as attached to the body 12 [112], the outer surface of which forms one of the electrodes. The '864 Patent does teach the advantage of having the electrode tip 132 somewhat remote from the place of attachment in order to have it remain free of the adverse effects of fibrosing which generally occurs at the site of attachment, thereby being able to maintain low threshold voltages. There is no indication in the Patent '864 of the material comprising the wires, but the term "wire" in normal usage implies a metal which would conduct electricity.

The Court does not find that the '864 Patent discloses the equivalent of a nonconducting tine means "sufficiently pliant to prevent penetration of heart tissue" embodied in Claim 1 of the '501 Patent. Penetration of the heart tissue appears to be intended to effect fixation with remote manipulation (active fixation), i.e. "pulling" to complete the attachment if necessary.

The Rasor '864 Patent was cited by the Patent Examiner in the prosecution of the '501 Patent.

The Court finds that none of the prior art references before the Court anticipates the tined endocardial lead embraced by Claim 1 of the '501 Patent.

(3) *Obviousness*

While the ultimate question of patent validity is one of law, several factual inquiries must be made to determine obviousness under 35 U.S.C. § 103. *Graham v. John Deere,* 383 U.S. at 1. The Court must determine the scope and content of the prior art, the differences between the prior art and the claims of the patent-in-suit, and the level of ordinary skill in the pertinent art. *Id.* at 17.

The proper analysis of obviousness under § 103 involves a determination of whether one of ordinary skill in the art at the time of the Citron invention in 1972 would look at what the prior art available in 1972 disclosed and have found it obvious to combine references or portions thereof to arrive at the tined endocardial lead embraced by Claim 1 of the '501 Patent. One does not start with Claim 1 and go to the prior art to see if one can piece together the Citron-Dickhudt tined lead from the combination of older things. *See Application of Aufhauser,* 399 F.2d 275, 276-277 (C.C.P.A. 1966).

(a) *The Scope and Content of the Prior Art*

The scope and content of the Spickler et al. article, the Rasor slide presentation, the Rasor-Spickler development work and the Rasor '864 Patent is set forth *supra* in the Court's discussion of its impact on the requirement of novelty under 35 U.S.C. § 102.

In addition to these references, the following prior art references are deemed most pertinent by defendant Daig:

1. the Medtronic wedge-tip lead Models 6901 and 6907 (PX 30, PX 40);

2. United States Patent No. 3,635,223 to Klieman (PX 19);

3. United States Patent No. 2,704,076 to H. J. Larson (DX 35); and

4. Sample device as disclosed in the Larson '076 Patent (DX 36).

Wedged tip lead

Transvenously implanted endocardial leads with wedge or flange tips, such as Medtronic Model Nos. 6901 and 6907, were manufactured and sold by Medtronic by 1970. Other pacemaker companies also sold this type of lead, including General Electric. (*See* PX 18, G.E. Product Data Sheet). The wedge or flange tip is a conical shape made of silicone rubber designed to wedge into the trabeculae of the right ventricle to hold the electrode in electrical contact with the heart wall.

Medtronic brochures, (DX 18, p. 2 and DX 17, p. 8), copyrighted in 1970 and 1972 respectively, depict the flanged lead with an electrical conductor encased in silicone rubber, a material generally inert to body fluids, which terminates in an exposed electrically conductive tip made of platinum. The flange is nonconducting, made of silicone rubber. It extends from the encasing material away from the exposed tip. The brochures depict both the standard straight-sided lead and the flanged lead in the same drawings and in describing lead placement do not differentiate between how the two leads are held in the heart. Both are designed to wedge into the trabeculations in the apex. (See PX 30 and PX 40 for samples of Model Nos. 6901 and 6907).

Dr. Maloney was of the opinion that this is a non-fixation means, i.e. that the flange lead has no fixation mechanism. Mr. Friedman, on the other hand, was of the opinion that this is a passive fixation means. The G.E. Data Sheet states that the step in the flared tip assists in fixation. (PX 18, page 2).

Dr. Maloney testified that a high percent of right ventricular perforation (the body of the lead puts a hold through the myocardium and enters the pericardial space) in using flange tipped leads in 1975, 1976 and part of 1977 led the Mayo Clinic to discard use of this type of lead. Mr. Friedman was of the opinion that the flanged lead would be pliant and not cause perforation but would be sufficiently rigid to maintain its shape.

Reference to specific models of the Medtronic wedge leads was not made during the prosecution of the Citron '501 Patent. However, flange leads were cited in the section of the Patent entitled "Background of the Invention" in which the '501 Patent cites and briefly describes an article to Smyth et al. entitled "Permanent Transvenous Atrial Pacing, an Experimental and Clinical Study," *The Annals of Thoracic Surgery*, Vol. 11, No. 4, Apr. 19, 1971, pages 360-370. (PX 1, column 1, lines 28-44). The wedge lead is also disclosed in the Schaldach article entitled "New Pacemaker Electrodes" which is specifically cited by the Patent Examiner in the prosecution of the '501 Patent. (*See* PX 14, p. 32, Figure 7; PX 1). In addition, the Schmitt Patent 3,754,555, which was disclosed to the Patent Examiner during the prosecution of the '501 Patent by Medtronic's attorneys, briefly mentioned the wedge lead. (PX 20, column 1, lines 58-62; PX 2, p. 31).

Klieman Patent 3,635,333

The Klieman Patent, issued on January 18, 1972, discloses an embolectomy catheter for snagging blood clots. It has a balloon portion on the forward end with rearwardly slanted, rounded protrusions approximately one millimeter in length. The catheter is passed through an artery or vein until the balloon is pushed past the blood clot. Once the balloon is past the clot, it is withdrawn, with the protrusions on the balloon engaging the clot. The balloon may be inflated to adjust to the size of the blood vessel. The protrusions on the balloon are described as "round and sufficiently flexible to avoid damage to the vessel but are firm enough to hold onto the clot." (PX 19, column 2, lines 41-53). The catheter is repeatedly inserted and withdrawn from the vein or artery until the blood clot has been removed. The Court finds the Klieman Patent to be marginally analogous prior art since it teaches nothing of the purpose of the protrusions in holding the catheter in place. *See Mott Corp. v. Sunflower Indus.*, 314 F.2d 872, 878 (8th Cir. 1963). The Klieman Patent was not specifically cited in the prosecution of the '501Patent. However, it is classified in Class 128, subclass 348 which the Patent Examiner searched on February 4, 1974; July 16, 1974; and November 13, 1974. (PX 2, p. 56). Therefore, absent any evidence to the contrary, the Court finds that in the Patent Examiner's searches of Class 128, subclass 348, he considered the Klieman reference. *See E.I. DuPont de Nemours v. Berkley & Co., Inc.*, 620 F.2d 1247, 1266-1267 (8th Cir. 1980).

Larson Patent 2,704,076

The Larson Patent issued on March 15, 1955, is also classified in Class 128, subclass 348. It discloses a tubular dilator for insertion into the milk duct of the teat of a cow. An enlargement of the tubular stem of the dilator has a plurality of flexible fingers which bend when the dilator stem is inserted and once placed exert an outer pressure which assists in maintaining the dilator in proper position and prevents accidental removal of the dilator from the teat. The entire dilator is preferably formed of a flexible plastic material to prevent excessive discomfort to the cow. (DX 35 and sample device DX 36). As with the Klieman reference, this Patent was not specifically cited by the Patent Examiner in the prosecution of the '501 Patent. However, absent evidence to the contrary, the Court finds that in the Patent Examiner's search of Class 128, subclass 348, he considered the Larson reference. The Court finds it highly doubtful that someone looking for solutions to dislodgement problems with endocardial leads would look to the Larson Patent. *See Mott Corporation v. Sunflower Industries, Inc.*, 314 F.2d at 878. The Court would also note that Daig's expert, Mr. Friedman, gave no testimony as to the Larson reference.

The following patents and publications were specifically cited by the United States Patent and Trademark Office during prosecution of the Citron et al. '501 patent (*See* PX 1, p. 1).

(a) United States Patent 2,854,983 to Baskin (PX 4);

(b) United States Patent 3,348,548 to Chardack (PX 5);

(c) United States Patent 3,397,699 to Kohl (PX 6);

(d) United States Patent 3,516,410 to Hakim (PX 7);

(e) United States Patent 3,568,659 to Karnegis (PX 8);

(f) United States Patent 3,068,555 to Greyson (PX 9);

(g) United States Patent 3,717,151 to Collett (PX 10);

(h) United States Patent 3,719,910 to Avery (PX 11);

(i) United States Patent 3,815,608 to Spinosa et al. (PX 12);

(j) United States Patent 3,835,864 to Rasor et al. (PX 13) discussed by the Court *supra*;

(k) Schaldach, "New Pacemaker Electrodes", Trans: Am. Society for Artificial Internal Organs, Vol. 17, 1971, pp. 29-35 (PX 14);

(l) Wende, et al., "Neue intrakardicle Schrittmacherelektrode," Deutsche Medizinische Wochenschrift, Nr. 40, 2, Oct. 1970, pp. 2026-2028 (PX 15); and

(m) Pieper, "Registration of Phesic Changes of Blood Flow by Means of Catheter Type Flowmeter," Review of Sci. Instr., Vol. 29, No. 11, Nov. 1958, pp. 965-967 (PX 16).

In addition, the Schmitt Patent 3,754,555 (PX 20) was brought to the attention of the Patent Examiner by Medtronic's attorneys with an explanation as to how its teachings differed from those of the '501 Patent. (*See* PX 2, p. 31).

United States Patent LaLonde 3,059,213 (PX 17) and Russian Patent 260,819 (PX 21), which were not cited by the Patent Examiner, were also indicated by Daig to be pertinent prior art references before the hearing. However, during the hearing, Daig offered no testimony in regard to these references.

Of these remaining references, the Court will address the Schaldach reference entitled "New Pacemaker Electrodes", the Collett Patent, and the Schmitt Patent. None of the parties have presented testimony in regard to the other references apart from the testimony of Mr. Banner stating that the Patent Examiner had found the invention embraced by Claim 1 of the '501 Patent to be a patentable invention over each of the references before him, separately or in combination. The Court has reviewed these remaining references and finds nothing within them which would be more pertinent to the issue of obviousness than the prior art specifically addressed by the Court in this order. *Schaldach, "New Pacemaker Electrodes", Trans: Am. Society for Artificial Internal Organs, Vol. 17, 1971.*

The most pertinent disclosure in the Schaldach article for purposes of the patent in issue is that of a fixation technique for an atrial sensing catheter electrode. The fixation technique is comprised of small wire hooks which form part of the tip of the stimulating electrode. (*See* Figure 11, p. 34 and discussion, p. 33). Insertion of the electrode with this configuration requires the use of a pre-

curved guiding catheter to protect against injury to the veins, atrial wall and tricuspid valve. When the guiding catheter is removed the wire hooks are released and anchor between the trabeculae of the right auricle. (PX 4).

Collett Patent 3,717,151

The Collett Patent, filed on March 11, 1971 and issued on February 20, 1973, discloses a catheter device for retention within an animal for removing fluids, draining wounds or venting bloated animals. The catheter assembly employs an inner sleeve through which a trocar may be passed and an outer sleeve, shorter in length than the inner sleeve. The outer sleeve has a plurality of plastic fingers on the inner end, each connected to the outer sleeve by means of a plastic hinge which permits pivotal movement of the fingers. The sleeves and fingers are constructed from a rigid plastic.

When used with a trocar, for example in venting a bloated stomach, the trocar is passed through the inner sleeve and caused to penetrate the tissue at the desired location. The catheter is also passed through the tissue until the fingers of the outer sleeve extend within the cavity. The trocar is withdrawn and a pull back motion on the catheter frees the fingers which are pivoted until they compress against the wall of the stomach. The shoulder of each finger abuts the first sleeve preventing further pivotal movement. A collar is moved up on the outer sleeve until it abuts the outer surface of the skin of the animal. The skin is thereby compressed between the fingers on the inside and the collar on the outside which prevents accidental dislodgment. When it is time to withdraw the

catheter, the pivotal capacity of the fingers prevents hindrance of removal.

Most pertinently, the Collett Patent states that the catheter assembly, without using a trocar, could be conducted through a blood vessel and lodged in place within the heart. (PX 10).

Schmitt Patent 3,754,555

The Schmitt Patent, entitled "Controllable Barbed Intracardial Electrode", was filed on October 5, 1971 and was issued on August 28, 1973. It discloses a transvenous intracardial electrode which has a movable piston within the body cavity of the electrode. The piston carries resilient prongs that are extendable through channels or holes in the tip of the head of the electrode at a forward angle to the outside of the electrode. By exerting force on the piston, the prongs are advanced into the myocardium to secure the electrode in place. The prongs are retracted when tension is exerted on the piston. The prongs are preferably constructed of nylon or metal (stainless steel) covered with insulating material and the preferred number of prongs is four. (PX 20).

(b) *Differences Between the Citron '501 Patent and the Prior Art*

The prior art discloses various endocardial leads which have an electrical conductor encased in material generally inert to body fluids that terminates at an exposed electrically conductive electrode tip. Figure 12 of the Rasor Patent discloses the advantage of having the fixation mechanism of the electrode extend away from the encasing material

and away from the electrode tip in order to avoid the effects of fibrosing at the main point of electrical stimulation. Figure 4 of the Rasor Article discloses this as well. The wedged lead discloses the use of silicone rubber for construction of the flange portion of the lead which would be nonconducting. The Klieman reference (embolectomy catheter) discloses the use of pliant protrusions sufficiently firm to snag blood clots without damaging blood vessels but teaches nothing in terms of fixation. The Collett reference discloses a catheter assembly utilizing fingers to assist in holding the catheter in position, possibly in the heart, which are capable of pliancy due to their hinging nature. The Larson reference discloses the advantage of using a plurality of flexible fingers in a teat dilator.

None of the prior art references disclose an endocardial lead utilizing an artificial means to effect passive firm fixation in the trabeculae like the '501 tines which are rigid enough to maintain an acute angle when unrestrained yet pliant enough to prevent penetration of the heart tissue. The wedge, although not intended to penetrate heart tissue and perhaps adding some slight fixation capability beyond the straight-shanked leads, depends upon the build up of tissue to effect firm fixation. In contrast, the '501 tines provide firm artificial passive fixation prior to tissue build-up.

A number of the prior art references dealing with endocardial leads recognize lead dislodgment as a problem. However, they do not teach non-penetrating passive fixation to resolve this problem. The Rasor Patent, Figure 4 of the Spickler et al. article, the Schaldach article and the Schmitt Patent disclose fixation techniques intended to penetrate heart tissue with remote manipulation contemplated to

assist in completing firm fixation, thus constituting active fixation as opposed to the passive fixation of the Citron '501 lead. The Spickler et al. article does disclose radiating fingers which were intended to catch in the trabeculae but which were consistently rejected by Drs. Spickler and Rasor throughout their work in lead development. Figure 2 and the description thereof itself disclose nothing as to the fixation capacity of the fingers or whether the fingers would penetrate heart tissue. The article simply summarily dismisses the use of the radiating fingers. The Klieman, Collett and Larson references, although they teach the use of pliant protrusions, disclose nothing about the ability of these protrusions to effect firm passive fixation in the trabeculae in order to hold an electrode tip in contact with the heart wall. The Collett reference does mention the possible use of the catheter in the heart. However, the method for fixation within the heart would not bring an electrode in electrical contact with the heart wall but would hold it away from the heart wall. In addition, the pliant protrusions in the Collett reference depend upon the inner sleeve and collar to hold them in position.

(c) *The level of Ordinary Skill in the Art*

The development of pacemaker leads is not a purely engineering task nor a purely medical task. In general, the structure of a prototype for a new lead does not reveal whether a lead will function successfully in its intended environment. Usually fairly extensive animal testing is necessary if a lead design is new to determine if it will perform as intended followed by clinical evaluations by physicians in human patients prior to marketing.

Mr. Citron had a master's degree in electrical engineering when he was hired by Medtronic and assigned the task of developing an atrial pacing system. In preparation for this task, Mr. Citron studied the anatomy of the heart. Mr. Dickhudt, the co-inventor, was educated in mechanical engineering. Mr. Friedman, who was employed by Medtronic in 1972 in various areas including design leads for neurostimulation, had a graduate degree in biomedical engineering at the time. Mr. Friedman also had taken specific courses in anatomy and physiology while in graduate school. Mr. Friedman's testimony indicates that Medtronic offered courses to its employees which taught basic skills in cardiology. In addition, he was an instructor in bioelectricity at Medtronics which dealt with the electrophysiology of the heart. Mr. Friedman's testimony indicates that his role as an instructor at Medtronic necessitated greater knowledge in electrophysiology than would otherwise be required. Mr. Shearon, Vice President of Clinical Research at Medtronics, testified that many of the problems relating to the use of pacemaker leads are discovered by physicians in treating patients. Dr. Maloney, a cardiologist with the Mayo Clinic who was knowledgeable and experienced in the use of pacemaker leads in 1972, testified that generally physicians are knowledgeable in surgical techniques and in the anatomy and physiology of the heart, but they do not normally have training in engineering.

The Court finds that the hypothetical person skilled in lead design in 1972 probably would have had credentials commensurate to that of Paul Citron, i.e. a master's degree in electrical engineering coupled with a basic knowledge of the anatomy and physiology of the heart. In part, the Court bases this finding on the fact that it seems unreasonable that

Medtronic, a leader in the pacemaker industry, would assign one without at least the ordinary level of skill in the art the task of developing an atrial pacing system which involved lead design. Mr. Friedman's knowledge of anatomy and electrophysiology would have surpassed that of one ordinarily skilled in lead design in 1972.

Mr. Friedman testified that the '501 tined lead would have been obvious to one skilled in the art in 1972 in light of the teachings of the Spickler et al. article combined with the well-known use of silicone rubber in wedged or flanged leads on the market at that time. Dr. Maloney testified that it would not have been obvious in 1972 that the '501 tined lead would solve the problem of lead dislodgement. Mr. Citron testified that it was not obvious to him or Mr. Dickhudt in July of 1972 that the '501 tined lead would resolve the problem of lead dislodgement.

The evidence indicates that physicians were skeptical of the capabilities of the '501 tined lead until clinical studies established its success in resolving the dislodgement problem.

It is uncontroverted that Mr. Friedman was asked to resign from Medtronic in 1972 and that at this time Paul Citron was Mr. Friedman's supervisor. The Court finds Mr. Friedman's testimony that the '501 tined lead would have been obvious in 1972 in light of the Spickler et al. article and the wedged lead to be less than credible.

The Court finds that the evidence of the work done by Drs. Rasor and Spickler is highly probative that the '501 tined lead in fact would not have been obvious to one of ordinary skill in the art in 1972. In the Spickler-Rasor article (PX 22), they specifically recognize the problem of dislodgement with existing conventional leads. Yet, they rejected the radiating fingers as an attachment technique in 1970

and continued to reject it throughout their work in lead development up through 1976. The devices designed by Rasor and Spickler to effect firm attachment for conventional electrodes are tissue penetrating mechanisms. They never once attempted to use the radiating finger attachment technique in conjunction with a transvenous lead. Their report "Low Threshold Attached Electrode" (PX 91 discussed *supra*), indicates that the radiating finger technique was specifically rejected for transvenous leads.

Dr. Rasor had a doctorate in physics. (DX 22, pp. 7-8). Dr. Spickler had a master's degree in biomedical engineering and a doctorate in physiology (DX 24, pp. 8-9). Their skill in the art was greater than one with ordinary skill in the art in 1972. Yet, the evidence indicates that the '501 tined lead was not an obvious solution to them for lead dislodgement. Dr. Spickler testified that he thought they probably were attempting to develop a non-tissue penetrating mechanism in their experiments with the radiating finger concept discussed *supra*. However, this approach was tested, continually rejected and abandoned. *See Lockheed Aircraft Corp. v. United States,* 553 F.2d 69, 78 (Ct. Cl, 1977).

With hindsight and the benefit of the patent-in-suit, one can go to various prior art references and select different elements embraced by Claim 1. However, the Court finds that the tined lead embraced by Claim 1 of the '501 Patent would not have been an obvious combination to one of ordinary skill in the art in 1972.

The Court finds that there is clear and convincing technical evidence that establishes the validity of Claim 1 of the '501 Patent.

Other Indicia of Unobviousness

In *Graham v. John Deere Co.*, 383 U.S. at 17, the United States Supreme Court held that secondary considerations such as commercial success and long felt need and the failure of others might also be relevant inquiries as to the issue of obviousness. The Court does not find these considerations necessary to its determination of the validity of the '501 Patent. However, the Court would note that the evidence shows that Medtronic has enjoyed substantial commercial success attributable to the invention of the '501 tined lead. (*See* PX 39). In addition, Cordis Corporation and Cardiac Pacemakers, Inc. have accepted licenses under the '501 Patent. (*See* DX 38 and DX 39). Dr. Maloney testified that the tined endocardial lead is now the lead of choice in the medical profession. The evidence also shows that the tined lead provided a long felt need for reduced dislodgement in endocardial leads.

Prior Adjudication of Validity

Medtronic also relies upon an adjudication of its German Utility Model Patent No. 75 04 819 to establish the validity of the '501 Patent. The Court finds that this adjudication is not sufficient to establish the validity of the '501 Patent beyond question. Mr. Rooney, Medtronic's patent counsel, acknowledged that German Utility Patents are issued without the same consideration given to novelty or prior art as required for patentability in this country.

Infringement

In determining whether or not the accused Daig leads infringe the '501 Patent, resort must be had in the first

instance to the words of Claim 1 which Medtronic alleges has been infringed by Daig. If the accused Daig leads fall clearly within the Claim, literal infringement is made out. *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950). Absent literal infringement, infringement may be established under the doctrine of equivalents if the accused divices perform substantially the same function in substantially the same way to achieve the same result as the claimed invention. *Id.* at 608. *See also Farmhand, Inc. v. Laham Mfg. Co., Inc.*, 568 F.2d 112, 115 (8th Cir. 1978), *cert. den.* 436 U.S. 1913 (1978).

The first issue to be resolved in determining infringement is the scope of Claim 1 of the '501 Patent which is claimed to be infringed. *See* descussion *supra*. The parties dispute whether the tines embraced by this claim are limited to the longer projections depicted in the patent drawings or whether the "tine means" also embrace the shorter stubby tines found in later models produced by Medtronic.

Mr. Banner testified that the following models of Medtronic leads are using the invention as claimed in Claim 1 of the Citron '501 Patent: Model 6961 (PX 33), Model 6951 (PX 31), Model 6971 (PX 37), Model 6990 (PX 32) and Model 6991 U (PX 38). Mr. Banner found correspondence of the elements of Claim 1 in each of these lead models. Models 6961/62 and 6971/72 utilize shorter stubby tines than the tines depicted in the drawings in the '501 Patent.

Daig contends that the expression "tine means" in Claim 1 of the '501 Patent must properly be limited to the tines in the form of longer projections as shown in Figure 1 of the '501 Patent. Daig asserts that when "tine means" is construed with respect to the specification, drawings and

the file wrapper, it is clear that Claim 1 was allowed only on the longer tines as depicted in Figure 1.

Claim 1 of the '501 Patent was rejected several times by the Patent Examiner as obvious in light of the Schaldach and Collett references discussed *supra*. The Court finds that patentability of Claim 1 was granted over these references on the basis that the tines of Claim 1 in cooperating with heart tissue to hold the electrode tip in position are sufficiently rigid to maintain an acute angle when unrestrained but sufficiently pliant to prevent penetration of the heart tissue.

The work performed by the tined lead of Claim 1 is to hold the electrode tip in contact with the heart wall to provide proper electrical stimulation to the heart to allow proper heart pacing. It is achieved by utilizing non-conducting pliant tines that extend away from the encasing material of the electrical conductor and away from the tip at an acute angle with the encasing material to cooperate with the heart tissue without penetration of the heart tissue.

The Court finds nothing within the file wrapper or Claim 1 which limits the scope of the "tine means" to the longer tines depicted in Figure 1 of the '501 Patent. The Court finds that Claim 1 is not limited to the specific embodiment disclosed in the specifications and drawings but also covers a reasonable range of equivalents of the claimed invention which cooperate with heart tissue to hold the electrode tip in position but with the limitation that the tine means are sufficiently pliant to prevent penetration of heart tissue but sufficiently rigid to maintain an acute angle when unrestrained. 35 U.S.C. § 112. *Lockheed Aircraft Corp. v. United States*, 113 F.2d at 79.

The Court finds that the evidence establishes beyond

question that the models of endocardial tined leads sold by Daig as exemplified by plaintiff's Exhibits 56, 58, 60 and 62 infringe Claim 1 of the '501 Patent.

Mr. Friedman, Daig's own expert, found correspondence of all of the elements of Claim 1 of the '501 Patent in the Daig ventricular tined lead (PX 56); in the Daig atrial J silicone tined lead (PX 58); the Daig urethane tined wedge lead (PX 60) and in the Daig atrial J urethane tined lead (PX 62). Mr. Fleishhacker, President of Daig, also found correspondence of the elements of Claim 1 of the '501 Patent in the aforementioned models as did Mr. Banner. Mr. Bartz was of the opinion that Daig's ventricular tined lead and its urethane tined wedge lead do not infringe Claim 1 of the '501 Patent.

In regard to Daig's ventricular tined lead (PX 56 and 57), which is disclosed and described in United States Patent No. 4,236,529 to Little, Mr. Bartz was of the opinion that there is no literal infringement of Claim 1 of the '501 Patent because the tines, which are fin-shaped, are not adjacent or close to the electrode tip and do not extend away from the casing. Rather, they extend from the cylinder core which is part of the tined means. In addition, Mr. Bartz was of the opinion that this lead differs functionally so as to preclude infringement under the doctrine of equivalents. In particular, the fin-like tines move laterally during insertion and withdrawal and their pliancy is determined by design and not just material.

In regard to Daig's urethane tined wedge lead (PX 60) Mr. Bartz was of the opinion that there is no literal or equivalent infringement as it has a differing structure and function. In particular, the wedge-shaped member has three or four tines which extend from the rearward part of

the flange which are not adjacent or close to the electrode tip.

Mr. Bartz agreed that the tines of both the ventricular tined lead (PX 56 and 57) and the urethane tined wedge lead (PX 60) cooperate with heart tissue in order to hold the tip in position. The parties do not dispute and examination of these exhibits plainly shows that the tine means are sufficiently pliant to prevent penetration of heart tissue and yet sufficiently rigid to maintain an acute angle when unrestrained.

The Court finds that Daig's ventricular tined lead (PX 56 and 57) and Daig's urethane tined wedge lead (PX 60) perform substantially the same function in substantially the same way to achieve the same result as the Citron-Dickhudt invention embraced by Claim 1 of the '501 Patent. The Court also finds that Daig's endocardial tined leads as exemplified by plaintiff's exhibits 58 and 62 embody each element of Claim 1 of the '501 Patent and also function in substantially the same manner to achieve substantially the same result defined in Claim 1.

Allegations of Fraud on the Patent Office

Daig has also asserted that Medtronic committed fraud on the Patent Office by failing to disclose Medtronic lead models 6901 and 6907 (wedged-tip leads), the Spickler et al. article (PX 22) and the Rasor slide presentation.

A finding that a patent was procured by fraud must be based on clear, convincing and substantial evidence. *Clark Equipment Co. v. Keller,* 570 F.2d 778, (8th Cir. 1978) *cert. denied,* 439 U.S. 825 (1978); *Norton v. Curtis,* 433 F.2d 779, 797 (C.C.P.A. 1970). Daig's evidence on this issue falls far short of that standard.

The Court has previously discussed references to the wedge lead which were before the Patent Examiner in the prosecution of the '501 Patent, *supra* at page 36 of this memorandum order. The Court again notes that in the section entitled "Background of the Invention" of the '501 Patent, the wedged type lead is specifically described. In part it states: "There was no attempt to artificially secure the electrode tip in position, *the atrial traveculae and the shape of the catheter being relied upon to maintain it in location until the heart tissue itself enveloped and fixed the tip.*" (Column 1, lines 28-44) (emphasis added).

In regard to the Spickler et al. article, the evidence does show that Medtronic maintains a substantial technical library which contains such journals as the *Journal of Electrocardiology* in which the Spickler et al. article was published. In addition, Mr. Friedman testified that this article was received by Medtronic and circulated to Medtronic personnel between 1970 and 1972. Mr. Friedman recalled having viewed the article at this time because he thought it would be of interest to a colleague of his in Yugoslavia who was working on a capsule similar to the capsule depicted in the Spickler-Rasor article. In addition, he recalled that several people at Medtronic, one of whom was Dr. Alan Kahn, had specifically brought the article to his attention thinking it would be of interest to Mr. Friedman given his work on nerve stimulation.

Mr. Citron testified that he did not know of the article until sometime in 1979 or 1980. There is no evidence that anyone at Medtronic thought the Spickler-Rasor article or the IECEC slide presentation was in any way material to the patentability of the '501 Patent.

The Court has previously found that the Spickler-Rasor

article does not disclose the invention embraced by Claim 1 of the '501 Patent and in no way defeats the patentability of the '501 Patent. The IECEC slide presentation disclosed no more than the article. In addition, the Court does not find the Spickler-Rasor article to be more pertinent than the Rasor Patent which was before the Patent Examiner. There is no basis for finding that the '501 Patent was obtained by fraud or inequitable conduct.

The Threat of Irreparable Harm

Daig is in Chapter 11 reorganization proceedings. No plan of reorganization has been approved. Daig's schedule of assets filed with the Bankruptcy Court in 1981 show assets of $3,414,892.00 and liabilities of $7,925,988.73. (PX 82). Of the liabilities, approximately $310,535.80 are listed as owing to creditors with priority and $7,615,452.93 are listed as unsecured debts without priority. Mr. John Fleischhacker, President and Chairman of the Board of Daig, testified that the figures in the report have not changed significantly. In the Bankruptcy Court's Order of April 15, 1982, the Court stated that the status and priority of Medtronic's possible claim for infringement is subject to speculation and not assured in whole or in part.

Total sales of allegedly infringing Daig leads from June 1981 through November 1982 was $1,154,830.60 representing 41.2% of Daig's total sales on all products for this time period. (DX 20). A portion of the amount of accused lead sales for this time period were to original equipment manufacturers (OEM's) who are currently licensed by Medtronic or are in pending litigation with Medtronic defending against the '501 Patent. (See confidential exhibit DX 48). Daig's pretax profits for the fiscal year October 1, 1981

through September 30, 1982 and for the six month period from June 1, 1982 through November 30, 1982 are set forth respectively in confidential exhibits DX 61 and 62. The figures in these exhibits are unaudited, but Mr. Fleischhacker stated that to the best of his knowledge, they are accurate. Mr. Fleischhacker testified that Daig's bank debt has been reduced from approximately $400,000.00 to approximately $200,000 which Mr. Fleischhacker anticipates eliminating by November of 1983. Mr. Fleischhacker also testified that Daig has totally paid off its lease obligations on various machinery and equipment, and that Daig has a cash reserve on deposit in the amount of $100,000 which is not currently required for ongoing expenses.

Medtronic has granted licenses on the '501 Patent to Cordis and CPI at the royalty rate of ten percent of the net sales price. (*See* DX 38 and DX 39). Daig contends that the evidence demonstrates that it could respond in monetary damages at this established royalty rate, and therefore, Medtronic is not being irreparably harmed.

The Court finds that despite Daig's improved earnings as reflected in confidential exhibits DX 61 and 62, there is a strong likelihood that Medtronic will not receive adequate monetary compensation for its past and continuing damages.

Balance of Hardships and Public Interest

Defendant, Daig Corporation, was started in 1974 by John Fleischhacker. In 1976, Daig hired Richard Little who designed the Daig tined lead. Mr. Little had previously been employed by Medtronic in cardiovascular leads design and development. The evidence establishes that at least as of November 20, 1978 during the development of the Daig tined lead, Daig knew of the Medtronic tined lead. Mr.

Fleischhacker testified that Daig spent approximately $5,000 in research and development expense on its tined lead. To Mr. Fleischhacker's knowledge, Daig did no clinical testing of its tined lead before it was marketed. The first Daig tined leads were advertised by Daig by February of 1979 and were on the market at least by May of 1979. United States Letters Patent Little 4,236,529 entitled "Tined Lead" issued on December 2, 1982 in the name of Richard L. Little on an application filed on February 21, 1979. The Little Patent lists Daig Corporation as the assignee of the Little Patent.

Medtronic has been involved in cardiac pacing for approximately 25 years. In 1982, Medtronic had sales of $300,000,000 based primarily on the evolution of cardiac pacing. Its research and development expense for 1982 exceeded $30,000,000. Typically, eight to nine percent of Medtronic's annual gross revenues are reinvested in research and development. The estimated research and development expense of the Medtronic tined leads embraced by Claim 1 of the '501 Patent is at least $500,000.

The Court is not unmindful that the grant of a preliminary injunction may well preclude a successful reorganization on the part of Daig Corporation. However, given the clear and convincing technical evidence, brought forth during a two week hearing, which establishes the validity of the '501 Patent and the strong finding of infringement by Daig of the '501 Patent, the Court finds that the equities favor granting a preliminary injunction to Medtronic. It seems an inescapable conclusion that Daig has reaped the benefits of a product and market developed largely through the efforts of Medtronic. To allow Daig to continue selling products which the Court finds do clearly infringe Claim 1 of the '501 Patent would in effect be granting Daig a royalty-free license for the benefit of its current creditors

while Medtronic is prohibited from pursuing a claim for damages at this time.

In addition, the Court finds that the public interest is served by granting a preliminary injunction to Medtronic. As the Court stated in *Eli Lilly and Co. v. Premo Pharmaceutical Labs,* 630 F.2d 120, 137-138 (3rd Cir. 1980):

> In enacting the patent laws, Congress recognized that it is necessary to grant temporary monopolies on inventions in order to induce those skilled in the 'useful arts' to expend the time and money necessary to research and develop new products and to induce them 'to bring forth new knowledge'."

The record demonstrates that Medtronic invests an amount in research and development in excess of that generally found in the industry, and public policy supports granting a preliminary injunction to Medtronic.

ORDER

Based upon the findings of fact and conclusions of law set forth herein, it is hereby ORDERED:

That Daig, its officers, directors, agents, employees and all acting in concert with it or through them are preliminarily enjoined during pendency of this action from making, using or selling silicone tined leads, atrial J tined leads (urethane), atrial J tined leads (silicone), tined wedge leads (urethane), or any other lead embodying the elements of Claim 1 of United States Letters Patent Citron et al. 3,902,501.

Dated: May 20, 1983.

/s/Paul A. Magnuson
United States District Judge

EDITOR'S NOTE

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86-385

Supreme Court, U.S.
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No. 86-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

DAIG CORPORATION,

Petitioner,

vs.

MEDTRONIC, INC., and
MEDTRONIC PUERTO RICO, INC.,

Respondents.

EXHIBITS SUPPLEMENT

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August 29, 1986

1986—Northwest Printing Co., 3010 2nd St. No., Minneapolis, MN 55411—588-7506

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Composite Prior Art Showing Wedge-tip Bipolar Lead, as Well as Rasor, Fountain, and Klieman Patent Drawings Ex.-55

United States Patent [19]

Citron et al.

[11] **3,902,501**

[45] **Sept. 2, 1975**

[54] **ENDOCARDIAL ELECTRODE**

[75] Inventors: **Paul Citron**, New Brighton; **Eugene A. Dickhudt**, St. Paul, both of Minn.

[73] Assignee: **Medtronic, Inc.**, Minneapolis, Minn.

[22] Filed: **June 21, 1973**

[21] Appl. No.: **372,269**

[52] U.S. Cl. ..... **128/418**; 128/404; 128/419 P

[51] Int. Cl. **A61n 1/04**

[58] Field of Search.... 128/418, 419 P, 404, 2.05 F, 128/407–409, 242–244, 325, 344, 345, 348–350, DIG. 16, 2.06 E

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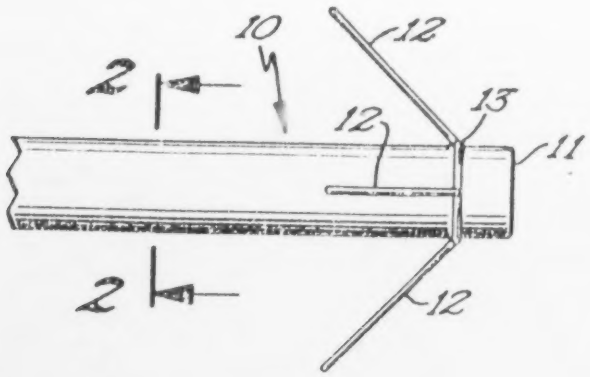
Primary Examiner—Richard A. Gaudet
Assistant Examiner—Lee S. Cohen
Attorney, Agent, or Firm—Lew Schwartz; Wayne A. Sivertson

[57] **ABSTRACT**

A medical electrode uniquely adapted for use as an endocardial electrode. An electrical conductor is encased in a material which is generally inert to body fluids and terminates at an exposed electrically conductive tip. A plurality of pliant tines extend from the electrode adjacent the tip and form an acute angle with the electrode body. Provision is made for holding the tines against the electrode body during insertion while allowing their release when the tip is in position. The released tines cooperate with the heart tissue, particularly the trabeculae found in the ventricles and the right atrial appendage, to maintain the electrode tip in position.

17 Claims, 13 Drawing Figures



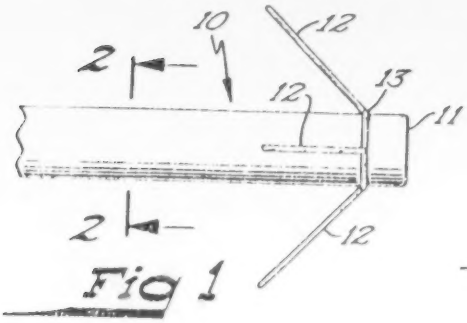


Fig 1

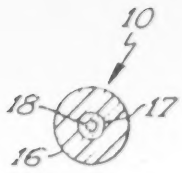


Fig 3

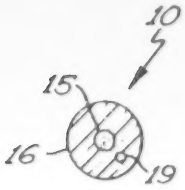


Fig 2

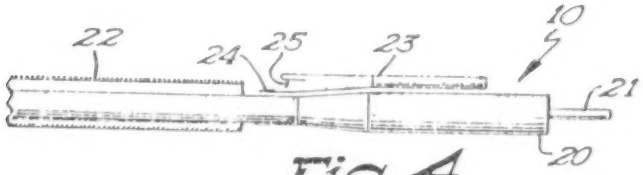


Fig 4

Fig 5

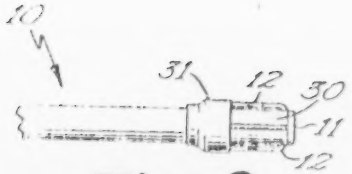
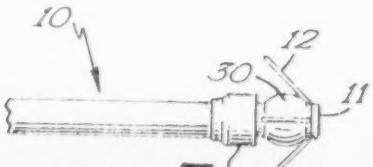


Fig 6



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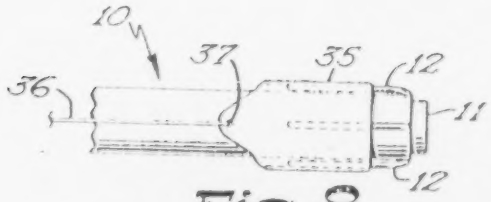

Fig 8

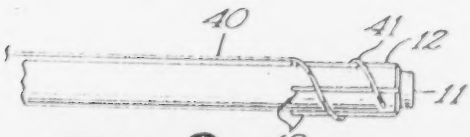

Fig 9

Ex.-2

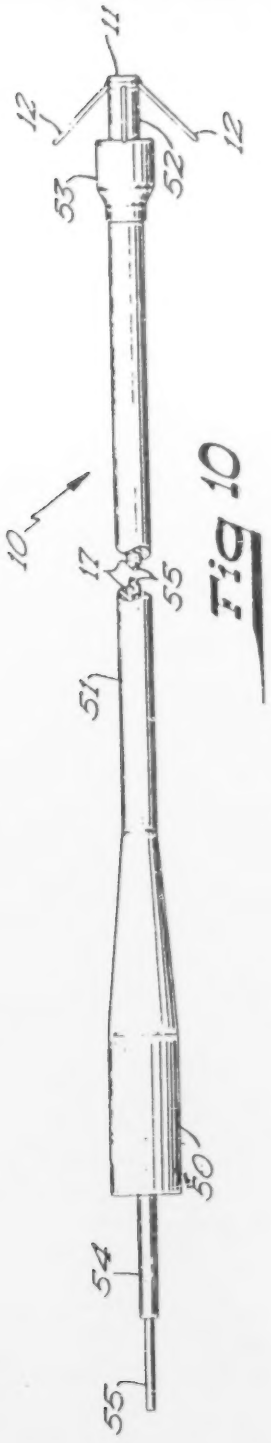

Fig 10

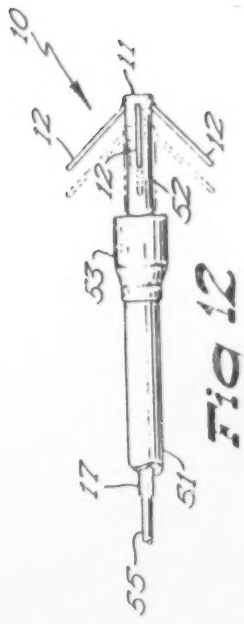

Fig 12

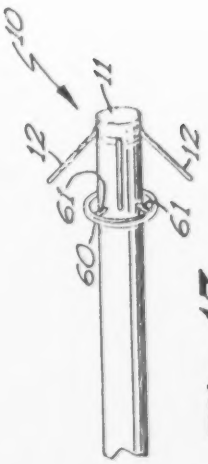

Fig 13

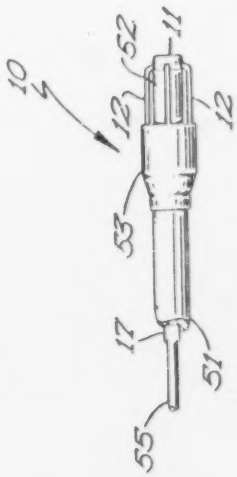

Fig 11

ENDOCARDIAL ELECTRODE

BACKGROUND OF THE INVENTION

Electrical stimulation of heart action is well-known and has been employed to counter a variety of heart dysfunctions. Dependent upon the particular dysfunction, optimal placement of the electrical contact point or points may vary. However, optimal electrode placement has often been sacrificed to other considerations such as minimization of the surgical risk and reliability of the electrode securement. To date, the greatest number of electrodes have been ventricular electrodes with the transvenous-endocardial approach coming into the fore in recent years.

The advantages of a reliable electrical contact with the atrium are well-known. Such a contact would allow atrial pacing or atrial synchronized pacing thereby preserving the contribution of the atrial contraction in the overall cardiac output. Additionally, an atrial contact would be advantageously employed for arrhythmia management and other purposes which may not be accomplished through ventricular electrical stimulation. For reasons well-known to those skilled in the art, the greatest advantages can be obtained through an electrical contact with the right atrium, the right atrial appendage providing a suitable site.

An attempt to accomplish transvenous or endocardial atrial pacing is described in Smyth et al. "Permanent Transvenous Atrial Pacing, An Experimental and Clinical Study", The Annals of Thoracic Surgery, Volume 11, No. 4, Apr. 19, 1971, pages 360–70. Here, a J-shaped catheter with a flange near the tip was inserted into the right atrial appendage through a transvenous approach. The catheter was straightened by the insertion of a stylet. When the stylet was withdrawn, the catheter assumed its preformed J shape for placement of the electrode tip in the atrial appendage. There was no attempt to artificially secure the electrode tip in position, the atrial trabeculae and shape of the catheter being relied upon to maintain it in location until the heart tissue itself enveloped and fixed the tip. The metal parts of the catheter may be radiopaque to facilitate placement by viewing through fluoroscopy.

A sensing atrial endocardial electrode is described in Portsmann et al., "P Wave Synchronous Pacing Using Anchored Atrial Electrode Implanted Without Thoracotomy", The American Journal of Cardiology, Volume 30, July 11, 1972, pages 74–76. A J-shaped applicator catheter was used to direct the electrode tip into the right atrial appendage. The electrode however, had two fine wire hooks positioned at its tip each ending in a relieving loop. The hooks were held back by the applicator catheter to spring out and anchor the electrode in the trabeculae of the right atrial appendage when the electrode tip left the end of the applicator catheter.

In the applicator catheter technique described above, the applicator catheter was radiopaque so that it could be viewed as it was inserted into the right atrial appendage. It is imperative with the double hook tip that the electrode be properly placed before the hooks are released. The placement was checked not only through fluoroscopy but also by extending the tip slightly beyond the end of the applicator catheter to take a threshold measurement. The tip had to be extended sufficiently to take an accurate measurement while still retaining the hooks within the applicator catheter. Because of its size, it is extremely difficult to accomplish this test measurement without also releasing the hooks. Additionally, the metallic nature of the hooks, their sharp points and spring action creates the possibility that the hooks may perforate the wall of the appendage if the catheter tip is not precisely positioned. Also, the configuration and rigidity of the hooks make it extremely difficult to remove the electrode without damage to the heart tissue while its metallic properties severely limit its utility as a pacing electrode.

SUMMARY OF THE PRESENT INVENTION

The present invention provides an electrode uniquely adapted for use as an atrial endocardial electrode. The electrode may be positioned in the right atrial appendage through the use of a J-shaped catheter known to the prior art. Alternatively, a J-shaped stylet may be employed which is held in a straightened position by the walls of the vein used to approach the heart, the stylet assuming its J-shape upon entry into the right atrium. A plurality of pliant non-conductive tines are provided at the tip of the electrode to cooperate with the heart tissue, particularly the trabeculae found in the right atrial appendage, to maintain the electrode tip in electrical contact with the heart tissue while allowing a removal of the electrode should that prove necessary. Provision is also made for holding the tines against the electrode body during insertion while allowing their release when the tip is in position and after a test threshold measurement. Although the electrode is discussed in the context of the right atrial appendage, it is suitable for use in any portion of the heart having the requisite cooperating tissue and may be employed as either a sensing or pacing electrode.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a preferred embodiment of the present invention.

FIG. 2 shows a cross section of the preferred embodiment of FIG. 1 taken along the line 2—2 in FIG. 1.

FIG. 3 shows a cross section of another preferred embodiment taken along the line 2—2 in FIG. 1.

FIG. 4 illustrates apparatus which may be used with the preferred embodiment of FIG. 1.

FIG. 5 shows a component of another preferred embodiment of the present invention.

FIG. 6 shows a preferred embodiment of the present invention which utilizes the component of FIG. 5, the tines being in a restrained position.

FIG. 7 shows the embodiment of FIG. 6 with the tines unrestrained.

FIG. 8 shows another preferred embodiment of the present invention.

FIG. 9 shows still another preferred embodiment of the present invention.

FIG. 10 shows a further preferred embodiment of the present invention.

FIG. 11 shows a portion of the preferred embodiment of FIG. 10.

FIG. 12 shows a portion of the preferred embodiment of FIG. 10.

FIG. 13 shows an additional preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring now to FIG. 1, there is shown a body member 10 terminating at an exposed electrically conduc-

tive tip 11 and a plurality of tines 12 extending at an acute angle from the body member 10 from a position adjacent the tip 11. The electrically conductive tip 11 may be of any material suitable for the environment; platinum-iridium, for example. The tines 12 are of a pliant material which is generally inert to body fluids; silicone rubber or polyurethane, for example. The tines 12 may be attached to the body member 10 in any convenient manner. For example, the tines may extend from, and be unitary with, a disc 13 which disc is held in position between the body member 10 and tip 11. Alternatively, the member 13 may be in the form of a ring which lies over either the body member 10 or tip 11 and is adhered thereto in any convenient manner. The tines 12 may take any angle with the body member 10, their purpose being to cooperate with the body tissue, particularly the trabeculae of the right atrial appendage, to maintain the tip 11 in electrical contact with the body tissue. It can be seen that an acute angle formed by the tines 12 and the body member 10 will have the greatest tendency to push against and become involved with the cooperating trabeculae and maintain the tip 11 in electrical contact. It has been found, that an angle of approximately 45° maintains the necessary electrical contact is a very efficient manner. Further, any number of tines may be used, three having proven to be adequate in most situations.

Referring now to FIG. 2 wherein there is shown a cross section of a preferred embodiment of the body member 10 of FIG. 1 taken along the line 2—2. In this embodiment, an elongated electrical conductor 15 runs substantially the length of the body member 10 and makes electrical contact with the tip 11. The conductor 15 is encased within a catheter 16 of a material which is generally inert to body fluids.

It is desirable that the catheter — conductor combination be made as flexible as possible. To accomplish this purpose while providing the necessary rigidity for insertion of the electrode, a stylet lumen 19 is provided, the stylet being within the lumen 19 during insertion of the electrode and being withdrawn after placement is accomplished. In a preferred embodiment, the stylet which is placed into the lumen 19 has a J configuration similar to that of the prior art applicator catheters. During insertion, the stylet is maintained in a "straightened" configuration by the walls of the vessel through which insertion is accomplished. When the electrode tip reaches the atrium, the stylet assumes its J configuration thereby allowing an easy insertion into the appendage. When the placement of the electrode tip is accomplished, the stylet is withdrawn. In this embodiment, the electrical conductor can be of any known type, one preferred form being a multistrand wire of platinum, for example, commonly referred to as "tinsel wire."

A second preferred form for the body member 10 is illustrated in FIG. 3. Here, the electrical conductor is a coiled member 17 which again runs substantially the length of the body member 10. The coil 17 is encased in a catheter 16 substantially identical to that shown in FIG. 2. The central portion of the coil 17 is left at least partially void to form a lumen 18 for the insertion of a stylet, the stylet serving essentially the same function in this embodiment as in the embodiment of FIG. 2. Further, in both the embodiments of FIG. 2 and FIG. 3, the lumens 19 and 18 may be lined with Teflon or any other appropriate material to facilitate the insertion and removal of the stylet.

Referring now to FIG. 4, there is again shown an electrode body portion 10 this time at the end farthest from the tip 11. In some applications, a pin type connection to an external stimulator or sensing device is desired. For this purpose, the body portion 10 commonly has an enlarged segment 20 from which extends the connecting pin 21. If it is desired to insert the electrode through the use of the J-shaped applicator catheter known to the prior art, the catheter must be made sufficiently large to slide back over the enlarged portion 20 or, alternatively, some other system for removal of the catheter must be provided. Here, the applicator catheter is shown at 22 of a size not sufficiently large to be withdrawn over the enlarged portion 20. A cutting tool 23 is shown adjacent the enlarged portion 20 and extending forward of the enlarged portion with a wedge 24 and a knife blade 25. The cutting tool 23 may be separate from the electrode body 10 or may be attached thereto in any convenient manner. In operation, the wedge portion 24 slips under the edge of the applicator catheter 22 and, as the applicator catheter 22 is drawn toward the cutting tool 23, the wedge will direct the catheter 22 into contact with the knife blade which will then cut and separate it thus allowing the removal of the applicator catheter over the enlarged portion 20.

The electrode shown in the embodiment of FIG. 1 may be successfully inserted into the right atrial appendage through a transvenous approach using the stylet technique of either FIGS. 2 or 3 or the J-shaped applicator catheter technique. In the applicator catheter technique, the tines 12 are not exposed during insertion. In the stylet technique of either FIGS. 2 or 3, however, the tines are non-restrained or extended during the entire operation. Although the electrode may be successfully positioned in this condition, it is found that the blood flow tends to draw the electrode tip into the ventrical. For this reason, some means of restraining the tines during insertion is desirable.

Referring now to FIG. 5, there is shown a balloon catheter similar to the balloon catheters used for other applications. Specifically, the catheter body 10 has a portion 30 which is inflatable from an end 32. The inflation is accomplished through a lumen similar to the stylet lumen 19 and 18 of FIGS. 2 and 3 respectively. Indeed, the inflation can be accomplished through the stylet lumens 19 and 18, the lumens being made sufficiently large to accomodate the stylet while allowing a passage for air to inflate the balloon. The ballooning feature of the electrode body 10 may be accomplished in any known manner. Referring now to FIG. 6, there is shown an electrode having a body 10 and a tip 11 as described with reference to the embodiment of FIG. 1. The body 10 is composed of a balloon catheter as illustrated in FIG. 5 with the ballooning or inflatable part lying adjacent the tip 11. A hold down shroud 31 is positioned near the tip 11 and is adapted to receive at least the ends of the tines 12 to restrain them in a position wherein they overlie the inflatable portion 30 of the electrode body 10. With the tines in this restrained position, a stylet may be inserted into a lumen such as that illustrated in FIGS. 2 or 3 and the electrode inserted through a transvenous approach without any interference from the extended tines. When the electrode tip is believed to be in an acceptable position as viewed by fluoroscopy, a test measurement can be made. If the

site of the electrode tip proves satisfactory, the balloon 30 can be inflated from the end of the electrode still outside the body causing the tines to withdraw from the shroud 31 and extend into their normal unrestrained position as illustrated in FIG. 7. With the tines freed from the shroud 31 the inflating pressure can be released and the balloon 30 will deflate to a normal configuration. The shroud 31 may take any shape which can accept at least the end portions of the tines 12. A ring which is attached to the body by spaced tethers is an example of an obvious modification of the shroud 31.

An alternative shroud to the shroud 31 of FIG. 7 is illustrated at 35 in FIG. 8. This shroud 35 again is adapted to accept at least the end portion of the tines 12 to restrain them in a position wherein they overlie the body of the electrode 10. A line 36 is attached to the shroud 35 at 37, and when the tip is properly positioned, a force on the line 36 will cause the shroud 35 to withdraw thus freeing the tines 12 to assume their extended unrestrained position. A similar approach is illustrated in FIG. 9 wherein a stylet 40 is shown having a coiled portion 41 which coiled portion is wrapped around the tines causing them to lie flat against the body member 10. Again, when the tip 11 is properly positioned, the stylet will be withdrawn thereby freeing the tines for interaction with the trabeculae of the right atrial appendage, for example.

Referring now to FIG. 10, there is shown another preferred embodiment of the present invention. Specifically, there is shown an electrode body 10 composed of a connecting portion 50, a central portion 51 and an end portion 52 which lies between the tip 11 and the shroud 53. The cross section of the central portion 51 may be as illustrated in FIG. 3. That is, the electrical conductor is a coiled member 17 having a void lumen forming central portion 18, the conductor extending from the tip 11 back to the connecting portion 50. The connecting portion 50 is similar to that illustrated in FIG. 4 with the connecting pin 54 making an electrical contact with the electrical conductor 17 and having a lumen coincident with the lumen 18 of the conductor 17. With this configuration, it is possible to insert a stylet 55 through the end of the connecting pin 54 to abut the tip 11. Inasmuch as the electrical conductor is a coiled member it can be stretched or elongated by applying a pressure against the tip 11 with the stylet 55. Since the electrical conductor is typically uniform throughout its length, the location at which the electrode body will give or elongate can be controlled to the durometer or diameter of the electrode body, or both. For reasons to be explained more fully below, it is desired that the portion 52 of the electrode body 10 "give" before the central portion 51 or the connecting portion 50. Therefore, the portion 52 is illustrated as having a smaller diameter than either the central portion 51 or the connecting portion 50. Alternatively, the material comprising the portion 52 may have a lower durometer than either of the other portions of the electrode body 10 or it may have a lower durometer and diameter as desired.

FIG. 11 illustrates the embodiment of FIG. 10 with the tines 12 having at least their ends restrained by the shroud 53 in a manner substantially identical to that illustrated in FIG. 6. With the tines in their restrained position, the electrode can be inserted and positioned and when a proper positioning is obtained as described above, the stylet is forced against the tip 11 causing the portion 52 to stretch as illustrated in FIG. 12 thereby releasing the tines 12 from the shroud 53. With the tines released, the stylet is removed thereby allowing the portion 52 to assume its normal shape as illustrated in phantom at FIG. 12.

As stated with regard to the shroud 31 of FIGS. 6 and 7, the shroud 53 of FIGS. 10-12 may take the form of a ring connected to the electrode body by means of a plurality of tethers. Such a ring shroud is illustrated at 60 in FIG. 13. As can be seen, the shroud 60 has a ring or a "doughnut" configuration and is held in place by means of tethers 61 which perform essentially as the spokes of a wheel, the tethers 61 being positioned so as not to interfere with the restraining and release of the tines 12.

From the above, it can be seen that the present invention provides a new medical electrode uniquely adapted for use as an endocardial electrode. The electrode provides means for cooperating with the heart tissue, particularly the trabeculae of the ventricles and right atrial appendage, to provide an artificial fixation until such time as a natural fixation has occurred. The tines are of a pliant material which is sufficiently rigid to accomplish their purpose without having the snapping action and sharp points attendant in the prior art devices. Further, the present invention provides a system for positioning the electrode and making any necessary test measurements prior to its being finally positioned, the position of the tip with regard to the inserting devices being much less critical in the present invention than in the prior art devices because the tines may be selectively released independently of the insertion device.

Obviously, many modifications and variations of the present invention are possible in light of the above teaching. An example of such a modification would be to make the body member 10 or the tines 12, or both, radiopaque to facilitate the positioning by observation of the electrode through X-ray, fluoroscopy, etc. We have found that this can be accomplished through impregnation with carbon, barium sulfate or Tantalum. Of course, any suitable substance and method will be acceptable for this purpose. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

What is claimed is:

1. In an endocardial lead of the type having an electrical conductor encased in a material which is generally inert to body fluids, the conductor terminating at an exposed electrically conductive electrode tip, the improvement which comprises:

nonconducting tine means extending from said encasing material and away from said tip from a location adjacent said tip for cooperating with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said encasing material and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.

2. The lead of claim 1 wherein the improvement further comprises means external to said encasing mate-

rial for releasably restraining said tine means in a position overlying said encasing material.

3. The lead of claim 2 wherein said restraining means comprises shroud means for accepting at least the end portion of said tine means.

4. The lead of claim 3 wherein said restraining means further comprise means cooperating with said shroud means for effecting the release of said tine means at a point spaced from said shroud means.

5. The lead of claim 3 wherein the improvement further comprises:

inflatable means underlying said tine means when said tine means are in said restrained position; and

means spaced from said inflatable means for selectively inflating said inflatable means.

6. The lead of claim 4 wherein said tine means are non-metallic.

7. An endocardial lead which comprises:

elongated electrically conductive means;

flexible catheter means surrounding said electrically conductive means and having a lumen substantially parallel to and coextensive with said electrically conductive means;

electrically conductive tip means at one end of said catheter means and electrically connected to said electrically conductive means; and

nonconducting tine means extending from said catheter means and away from said tip from a point adjacent said tip means for cooperation with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said catheter means and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.

8. The lead of claim 7 further comprising means for releasable restraining said tines in a position wherein they overlie said catheter means.

9. The lead of claim 8 wherein said restraining means comprises shroud means for accepting at least the end portion of said tine means.

10. The lead of claim 9 wherein said restraining means further comprises means cooperating with said shroud means for effecting the release of said tine means at a point spaced from said shroud means.

11. The lead of claim 9 wherein said catheter means comprises a balloon catheter, the balloon underlying the tines when the tines are in the restrained position.

12. The lead of claim 11 wherein said elongated electrically conductive means comprises a coiled electrical conductor having a void central portion, said lumen coinciding with said void central portion.

13. The lead of claim 11 wherein said elongated electrically conductive means is positioned substantially at the center of the cross section of said catheter means and said lumen lies off the center of said cross section.

14. In a medical lead of the type in which an electrical conductor is positioned within a catheter and terminates at an exposed electrically conductive electrode tip, the improvement which comprises:

nonconducting tine means including a plurality of tines each extending from said catheter and away from said tip from a point adjacent said tip and forming an acute angle with said catheter for cooperating with heart tissue to hold the tip in position, said tine means being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue;

means for releasably restraining said tine means in a position wherein said tine means overlie said catheter; and

means underlying said tine means when said tine means are in said restrained position and inflatable from a point spaced from said restraining means for releasing said tine means from said restraining means upon inflation.

15. The medical lead of claim 14 wherein the angle formed by said tine means and said catheter is approximately 45°.

16. The medical lead of claim 14 wherein said pliant tine means material comprises a material which is relatively inert to body fluids, at least a portion of said material being radiopaque.

17. The medical lead of claim 16 wherein the radiopaque material portion is a material treated with a material selected from the group consisting of carbon, barium sulfate or Tantalum.

* * * * *

United States Patent [19]
Rasor et al.

[11] 3,835,864
[45] Sept. 17, 1974

[54] INT A-CARDIAC STIMULATOR

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[73] Assignee: Rasor Associates, Inc., Dayton, Ohio

[22] Filed: Sept. 21, 1970

[21] Appl. No.: 73,809

[52] U.S. Cl. ..... 128/419 P, 128/418, 128/421
[51] Int. Cl. A61n 1/36
[58] Field of Search ..... 128/404, 418, 419 P, 421, 128/422

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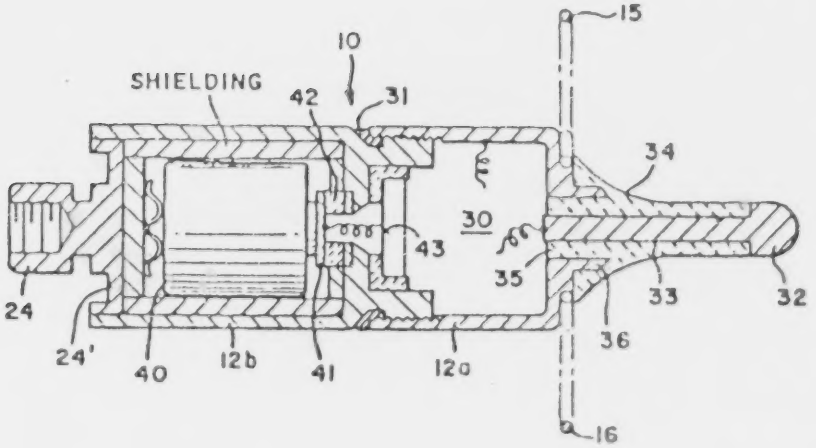
Primary Examiner—William E. Kamm

[57] ABSTRACT

A stimulator device for insertion in a living body and having particular advantage for intra-cardiac use comprising a structure having a body form of a size and configuration to enable its transvenous or transarterial insertion, the surface of said body form providing electrode means for contact with a portion of the living body to be stimulated by said electrode means, and means mounted to project outwardly of and peripherally of said body form including anchor portions locating in a position displaced from said electrode means and providing means for engaging in portions of said living body to establish said electrode means in a required position of use, said electrode means having in connection therewith means to energize the same once said body form is located in its required position of use.

7 Claims, 14 Drawing Figures



INTRA-CARDIAC STIMULATOR

BACKGROUND OF THE INVENTION

Implanted Pacemaker devices are now commonly employed for the long-term treatment of atrio-ventricular (A-V) block. Such Pacemaker devices commonly employ flexible leads which connect a remotely positioned power pack with electrodes which are placed in contact with or attached to the myocardium. The techniques of implanting and using such Pacemakers, and many Pacemaker which have been used experimentally and in practice, are described by Siddons and Sowton, *Cardiac Pacemakers* (1967), published by Charles C. Thomas, Springfield, Illinois, Library of Congress Card No. 67-12042. Pacemakers having energy sources responsive to heart movement are shown in U.S. Pat. Nos. 3,358,690 and 3,486,506.

Such Pacemakers, or other biological stimulators working on these principles, have inherently suffered from certain disadvantages. The leads to the electrodes are commonly routed through veins leading into the heart itself. The movement of the heart and normal activity of the individual tend to put a strain on these leads and may result in lead breakage or dislodgement of the electrodes. The leads themselves, retained in situ, are frequently a source of irritation and infection. Further, since the electrical contact with the heart is made at the point or region of mechanical support or implantation, the normal fibrosis of tissue at these regions often results in a marked increase power required to pace, known as an increase in threshold. For example, the threshold has been found to increase on the order of ten times its original value until a plateau is reached over a period of two to three weeks. This requires a correspondingly greater power input to the electrodes, in the minimum of 3:1 over threshold, in order to achieve consistent pacing.

The remote power pack itself is a cause of discomfort and often a cause of difficulty. It is commonly implanted in a subcutaneous pocket beneath the pectoralis major or within the abdomen. Again, this provides a further opportunity for infection. Difficulty has been encountered in preventing migration of the power pack. Further, surgery is required from time to time to expose and replace the power pack due to exhaustion of the mercury cells. Prior pacing devices which derive their energy from the heart movement or pressures have commonly required thoracic surgery for attachment to the epicardium, and have employed flexible leads to the electrodes.

SUMMARY OF THE INVENTION

The present invention is directed to a wholly selfcontained stimulator which is particularly adapted for use as a Pacemaker. It is contained within a package or housing which is sufficiently small to be implanted by catheter insertion (transvenous or transarterial) into a chamber of the heart where it is attached to the endocardium. The stimulating electrodes are formed integrally with the unit, without external leads, and thus make contact with the endocardium. As used herein, "catheter" refers to an inserting device embodying a sheath-like element of small bore tube form.

A Pacemaker device made according to the present invention is intended primarily for long-term use. It can be used without discomfort to the user. The likelihood of a failure due to dislodgement of electrode contact, increase of threshold, or occurrence of infection is substantially reduced. Failure due to electrode lead breakage is eliminated entirely. The device can be implanted by a catheter device and technique which require only minor surgery and temporary discomfort to the patient. It can be recovered if desired or, if failure should occur it may simply be left in place and a new device inserted.

In one form of the invention a nucleonic battery is employed for providing a power source to the pulse generator circuits contained within the housing. This arrangement provides for an overall life which may be well beyond the normal life expectancy of the patient. For example, Pu-238 has a half life of 86 years, while Pm-147, which may be preferred because of lower costs, has a half life of 2.7 years. Suitable electronics in the converting and pulse generating portion are available which operate efficiently over three or more half lives. Operation over such a large power range is made possible in part by the fact that the device of the present invention does not cause a material or significant increase in threshold, and therefore can continue to operate after decay to very low power levels.

Three forms of the invention are disclosed which employ a biologically energized power source and thus derive their power requirements from the body itself. Prior attempts have obtained insufficient power from normal heart activity to provide reliable and continuous pacing. However, the apparatus of the present invention is one which does not result in a significant increase in threshold power and accordingly reliable pacing may be affected over an extended period of time with modest lower power requirements. The energy required for each stimulation pulse may be in the order of one microjoule or less, corresponding to a total power input to the electronics on the order of six microwatts or less. The mechanical work which is available substantially exceeds this.

In one form of the invention, a movable wall or diaphragm transforms hemodynamic pressure into electric energy by means of a suitable transducer. In other forms of the invention, a mass is suspended in such a manner that movements of the heart set up a sympathetic or harmonic movement of the mass, and this movement may be electromechanically coupled to produce energy. For example, the transducer may comprise a permanent magnet in combination with a non-moving electric coil. In another form, the mass may be connected to stress a piezoelectric crystal.

The body or housing structure of the present invention may also be used as the electrode structure for existing Pacemakers, as it offers certain advantages over the endocardial electrodes which are presently in use.

Another important object of the invention is the provision of a bioelectric stimulator which is fully self-contained and implantable at the site of stimulation, and an improved electrode structure therefor.

A further object of the invention is the provision of a stimulator, heart Pacemaker, or an electrode structure for a Pacemaker, in which the region of attachment is spaced from the region of stimulation to avoid the adverse effects of tissue fibrosis at the region of attachment.

A further object of the invention is a provision of a catheter for inserting the Pacemaker or electrode as-

sembly therefor, as described above, and the further provision of the combination of a novel catheter and Pacemaker or electrode assembly therefor. The catheter is preferably a triaxial arrangement in which one of three concentric elements is removably secured to the body of the device, a second element forms a torque tube which may be used to assist in implanting the device and for removing the first element from the device, and the third element comprises an outer removable sheath which preferably extends at least partially over the body of the device during transvascular passage and may be employed to retain the body-attaching members on the device in a retracting or inoperative position until the device has been positioned, as desired. Thereafter, the sheath may be retracted to expose the body of tissue-attaching members, or extended to cover these members for removal of the device from the heart.

These and other objects and advantages of the invention will be apparent from the following description, the accompanying drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded view of the stimulator and catheter devices of the invention;

FIG. 2 shows parts of FIG. 1 in an assembled condition;

FIG. 3 is an enlarged sectional view, partially in diagrammatic form, of the stimulator of FIG. 1 adapted particularly for use as a heart pacer;

FIG. 4 is an end view of the device of FIG. 3;

FIGS. 5*a*, 5*b* and 5*c* are, respectively, diagrams illustrating the method of implanting the pacer using the catheter device of this invention;

FIG. 6 is a schematic drawing showing a pulsing circuit which may be used with this invention;

FIG. 7 is a diagram of a modified form of the circuit of FIG. 6 particularly adapted for use with a nucleonic or other varying power source;

FIG. 8 shows a modified form of the invention adapted to respond to hemodynamic pressure changes;

FIG. 9 is a block diagram of the pacer of FIG. 8;

FIG. 10 is a further modification showing a biologically powered pacer according to the present invention;

FIG. 11 is a still further modification showing another form of the biologically powered pacer; and

FIG. 12 is a modified catheter and an improved Pacemaker electrode assembly according to the teachings of this invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to FIGS. 1–4, a self-contained stimulator 10, particularly is adapted as a heart pacer, and a catheter 11 is adapted for use with such pacer. The pacer 10 is formed with an elongated capsule-like, generally cylindrical body 12. Preferably, the body 12 is formed exclusively on its outer surfaces of biologically compatable materials, the major portion of which may be stainless steel. While the outer surface of the body 12 is shown in the drawings as being formed essentially of smooth inert material, such as stainless steel, it is within the scope of this invention to provide the body with a compatible flocking material, such as a dacron weave to promote the formation of neointima once the unit has been implanted.

The device can be implanted in any of the four chambers of the heart where patho-physiology would be optimum for a particular patient. However, the preferred embodiment herein will emphasize implantation within the right ventricle where the greatest clinical and experimental experience has been concentrated to date. When the stimulator, or pacer 10, is adapted for implantation directly within a heart ventricle, it should have a maximum overall length not substantially exceeding 30mm and preferably in the order of 18mm or less. The diameter of the body 12 should not substantially exceed 10mm and is preferably 8mm or less. Such dimensions provide a self-contained Pacemaker which is sufficiently small to permit catheter transvascular insertion into a ventricle, and permit it to be received within such ventricle without disturbing the proper function of the heart.

The forward end of the body 12 is provided with means for attaching the pacer 10 to the myocardium. A preferred form of the attachment comprises a pair of oppositely directed spiral stainless steel attaching points or wires 15 and 16, as best shown in FIG. 4. The wires have inner ends attached to the circumference of the body 12 and free outer ends. These attaching wires are adapted to be retained in a retracted position in closely surrounding relation to the circumference of the body 12, but when released, spring out to the expanded or operative position, as shown.

Catheter means for transvenous implanting of the Pacemaker 10 preferably consists of the triaxial device illustrated generally at 11 in FIGS. 1 and 2. This arrangement comprises a central rod 22 which is formed with a threaded end 23 which is adapted to be attached or received with a suitable internally threaded nut 24 formed on the rear wall 24' of the body 12, as shown in FIG. 3. A torque tube 25 is slidably received over the rod 22 and, at its forward end, is formed with an internal socket portion 26 adapted to be received over the nut 24 in driving engagement with the Pacemaker 10. The catheter is further provided with an axially slidable sheath 27 which has a forward metallic end portion 28 of a diameter sufficiently to be received at least partially over the body of the Pacemaker 10. In use, the sleeve 28 substantially covers the Pacemaker and retains the attaching wires 15 and 16 in their retracted position substantially as shown in FIG. 2. The use of the catheter 11 is further described in connection with the illustration of FIGS. 5*a–c*.

This entire catheter system may be rigid with defined bends or may be flexible or may be steerable. In the preferred form, a central rod 22 and the torque tube 25 are flexible, while the forward end of the sheath 27 is formed with a predetermined bend as indicated at 27' in FIG. 5*a*. The bend which may be formed within 2–4 inches of the end of the catheter assembly, may have an angle of approximately 30° in order to permit the catheter and the attached Pacemaker to be steerable around corners and bends.

Referring particularly to FIG. 3, the Pacemaker 10 is shown as including a forward body portion 12*a* and a cylindrically continuous rear body portion 12*b*. The forward portion 12*a* is hollow and contains the electronic pulsing circuit 30, illustrative examples of which are shown in FIGS. 6 and 7. It has been found that relatively simple circuits are totally satisfactory and are in

fact preferred over the more complicated circuits shown, for example, in the reference text referred to under the Background section of the specification. The simpler circuits generally have lower losses and greater overall reliability. Such circuits can easily be fitted within the activity defined with the body section 12*a* without the necessity of reverting to microminiature or integrated circuits. However, such circuits permit even further miniaturization, but the overall size of the stimulator of this invention is dictated not so much by the circuit requirements but by the space requirements of the power source.

The body sections 12*a* and 12*b* may be threaded together and sealed as shown at 31, but it is within the scope of this invention to make the body 12 of simple one-piece construction. The rear wall 24' is preferred welded to the case 12*b* by electron beam welding. There is some advantage in the two-piece body construction of FIG. 3 in that it permits the body parts to be separated and adjustments to be made to the circuit prior to insertion.

One of the important advantages of the stimulator of the present invention resides in the fact that the pacing electrodes are formed integrally with outer surfaces of the body 12. To this end, the body portions 12*a* and 12*b* themselves define the positive pulsing electrode which, as previously noted, may be formed preferably of stainless steel. The negative pulsing electrode 32 is formed preferably of platinum and supported on a forwardly extending dielectric pedestal 33. The pedestal is preferably formed of an inert ceramic, defining a hollow co-axial insulator. The insulator 33 may thus have an outer curved surface 34 leading smoothly from the electrode end 32 and flaring outwardly at the body 12*a* to assist in guiding the device during insertion. A tubular portion 35 extends into the interior of the body 12*a*. The forward end of the body 12*a* is formed with an annular ledge 36 to provide support for the insulator and for the electrode 32.

The stimulating electrode 32 may also be of the differential current density type, known as the "Parsonnet Electrode" and described by George H. Myers and Victor Parsonnet in *Engineering in the Heart and Blood Vessels*, (1969) John Wiley & Sons, New York, N.Y.

The arrangement as shown has several important advantages. In the first place, it will be noted that, unlike prior devices, the electrodes do not themselves form or comprise the attaching devices. Rather, the pacing electrodes are well spaced axially from the barbs 15 and 16. Thus, once these electrodes have made reliable pacing contact with the heart tissue, they do not transmit the destructive forces of attachment and retention to this tissue, and they remain free of the adverse affects of fibrosis which invariably occurs at the regions of attachment or forcible retention. In devices where the electrodes themselves are directly attached or are forcibly retained by pressing against the tissue, an approximately 10 times increase in the threshold is not uncommon. This occurs over approximately a two to three week period subsequent to implanting and then reaches a plateau. Such a substantial increase in threshold requires a corresponding increase in power requirements simply to overcome the threshold and to effect reliable stimulation. The elimination of the cause of threshold rise permits reliable pacing with substantially lower power consumption.

Another important advantage of the construction of FIG. 3 is the total elimination of external flexible leads between the pacing circuit and the tissue to be stimulated. This then results in the elimination of the lead placement and breakage difficulties which are inherently associated with remotely positioned pacer circuit.

A further important advantage of the pacer of this invention is the fact that it can be reliably powered from a suitable nucleonic power source 40. There are available in the present state of the art a number of nucleonic conversion devices which may be contained within the physical dimensions of the body portion 12*b*, and suitably shielded and sealed therein. A preferred form of such device is a betavoltaic converter which is, in effect, a stack of semiconductor photocells which are coated with a radioactive material and which are irradiated by beta particles to produce an unidirectional current electric output. Beta sources may include Pm-147 which has a 2.7 years half life. It is within the state of the art to provide an electronic circuit which will operate effectively over more than three half-lives of such power sources within the volume available. The use of tritium, with a half life of 12.6 years, is also possible.

A power source 40 using radioisotope fuel may also be of the thermionic type, the thermoelectric type or the double conversion type. In the thermionic and thermoelectric types, heat from the radioisotopic fuel is transformed into electric power by electron transport through a thermionic diode or thermocouple respectively. In the double conversion type, radiation from the radiosotope fuel is employed to excite a light-emitting phosphor, and the photons in turn excite a semiconductor photocell. All three of these types can use Pu-238, which is a desirable fuel for biological applications and has a half life of 86 years. The choice of fuel and type of convertor will depend upon the cost of the source material and fabrication, the half life, and the efficiency of conversion as well as the shielding required. Suitable radioisotope-fueled batteries are made by Donald W. Douglas Laboratories, 2955 George Washington Way, Richland, Washington and sold under the tradenames "Betacel" and "Isomite," representing beta-voltaic and thermionic types respectively. While nucleonic power sources are preferred by reason of long life, it is within the scope of the invention to employ rechargeable batteries, or mercury cells. The latter may be satisfactory for short term pacing, in view of the relatively high overall efficiency of the device.

As shown in FIG. 3, an insulated plate 41 in contact with the power source is hermetically sealed by an insulator 42, and leads 43 extend to the circuit contained within the body section 12*a*. The case 12 is negative with respect to the power source but is positive with respect to the biological load.

The diagram of FIG. 6 illustrates one form of the pulsing circuit in which a power source 40 is shown as providing an output voltage of approximately 39 volts. This output is applied through charging resistor 44 and through the load 45 to a capacitor 46. The time required to charge the capacitor will depend upon the charging time constant of the circuit, and since the biological load 45 is normally less than 1,000 ohms it forms a small part of the total resistance in the charging circuit. However, as long as the load 45 is present the circuit will charge.

The transistors 48 and 49 comprise a transistor switch. This switch automatically becomes conductive to connect one side of the capacitor 46 to ground at some predetermined potential during the charging of the capacitor 46, and thus provides a low impedence grounding circuit permitting a discharge of the capacitor through the load 45. The peak load voltage may be 1.3 volts, and the transistor switch may be conductive for 3ms. Thereafter, the current through the switching circuit drops to the point where it becomes non-conductive, and recharging of the capacitor 46 resumes through resistor 44, at a repetitive rate depending on the R-C constant.

It might also be noted that since the capacitor 46 is charged through the biological load a current reversal takes place between the negative pulsing electrode 32 and the case 12 which has the effect of reducing or eliminating polarization which otherwise occurs when electrodes are pulsed in the same direction in an electrolytic solution.

The diagram of FIG. 7 is essentially for the same circuit as shown in FIG. 6 except for the addition of a constant current element 50 which may comprise a constant current transistor. This circuit is useful to maintain a constant pulse height and rate when the pulsing circuit is used with nucleonic power source whose output decays with time, or with biologically activated power sources whose output varies with the amount of biological activity.

The method of implanting the Pacemaker of the present invention using the improved catheter is illustrated diagrammatically in FIG. 5. The Pacemaker is assembled with the catheter 11 as shown in FIG. 2. The catheter is formed with a fixed or predetermined bend 27' about two to three inches from the end, of about 20°–40° to enable it to turn corners while it is being inserted. The insertion technique itself is essentially the same as currently in use for the transvenous implantation of endocardiac electrodes and other cardiac catherization procedures. The Pacemaker may, for instance, be inserted in the right external jugular vein and advanced through the superior vena cava and through the right atrium into the apex of the right ventricular cavity. This is the position illustrated in FIG. 5*a*. This is accomplished, of course, under fluoroscopic observation.

Prior to attaching the Pacemaker, the effectiveness of its resting position may first be observed with an electrocardiograph to assure that it is functioning normally and that it has captured the heart. The end 28 of the sheath 27 is preferably made of conductive material, such as stainless steel, so that the electrode formed on the body 12 will conduct through the sheath.

Having determined a proper position, the sheath may be partially retracted as shown in FIG. 5*b* to expose the barbs, and the torque tube 25 rotated clockwise to imbed the barbs in the myocardium. The entire Pacemaker, in this condition, will be wedged into the trabeculae making contact both with the case and with the tip electrode 32.

Once attachment in this manner is made, the torque tube 25 may be held against rotation and the rod 23 unscrewed from the internal threads in the nut 24. The entire catheter may then be extracted leaving the Pacemaker imbedded essentially as shown in FIG. 5*c*. The Pacemaker can be extracted from the heart by reversing the foregoing procedure.

The invention is not limited to heart pacing as such. Other examples of the direct implantation of the self-contained stimulator at the site of the stimulation without separate electrical leads include baropacing (stimulation of the baroreceptors in the neck or aortic arch), stimulation of the diaphragm for breathing (stimulation of the phrenic nerve), stimulation of the numerous sphincter muscles which control the flow of various body fluids and solids (at the sphincter site), and other such functions which have been shown to respond to electrical stimulation and which small size and absence of electrical leads would render feasible or more practical. In most such cases the self-contained stimulator described in FIG. 3 would deliver a pulse approximately every 20 milliseconds during activation of the biological function instead of about one pulse per second as in the cardiac Pacemaker. Activation of the pulse train could be accomplished by external command via an electromagnetic or magnetic signal from outside the body.

The invention is not limited to an arrangement which contains an internal source of power. In FIG. 8 there is illustrated an embodiment of the invention which is responsive to hemodynamic pressure. The body section 12*b* is replaced by a flexible or movable section which incorporates a rubber diaphragm or metal bellows 60 which moves under the influence of pressure changes within the heart cavity. Forces and motions arising from such pressure changes are applied to an electromechanical transducer 62 the output of which may be applied to a suitable energy storing circuit 63. The transducer may be of the magnetic induction type or may be a piezoelectric generator. The storage device 63 may be a diode-isolated full-wave-rectifier with capacitor storage. The energy thus stored is available for subsequent release to the stimulation electrodes by a pulse forming circuit substantially as previously described. The storage device will be kept charged by the succession of heart beats and therefore serves the function of the power source previously described.

For example, if the effective area of the movable section 65 is about ½cm², and moves 1mm under the influence of a 20 torr average pressure pulse, each beat would produce about 130 microjoules of mechanical work. Since less than 10 microjoules of electric energy is required for each pulse, a large margin of reserve power is available.

A circuit diagram at FIG. 9 shows an arrangement of the pacer of FIG. 8 adapted as a synchronous pacer, to obtain the benefits from synchronous pacing by slaving the unit to the atriol systole. After storing the large power pulse generated by the transducer during the ventricular contraction, the pulse-forming circuit is "armed;" i.e. it reaches a condition in which the next significant electrical signal from the transducer will cause the circuit to "fire" and deliver an electrical pulse to the stimulating electrodes. Therefore, the pressure impulse from the next atrial contraction is transmitted through the tricuspid valve to generate an electrical signal from the transducer which fires the circuit. The stimulated ventricular contractions thereby become synchronized with the atrial contractions. It may be desirable to construct the circuit so that "arming" is delayed until after the refractory period of the heartbeat to avoid premature firing by reverberations from the ventricular contraction. Also it may be desirable physiologically to provide a delay between the signal

from the atrial contraction and the Pacemaker output pulse, similar to the delay in the A-V node.

FIGS. 10 and 11 illustrate additional arrangements by means of which the heart movement itself can be used to provide a suitable source of energy. Observation has shown that an implanted Pacemaker undergoes transient displacements of about 1cm within a 24th of a second. Assuming constant acceleration, a 5mm displacement relative to the capsule over 1/24th second of an armature weighing 4 grams would produce a force of about 2500 dynes acting over this distance, to produce about 120 microjoules of work per beat, again substantially in excess of the requirements of the Pacemaker. Referring to FIG. 10, a mass 70 is mounted in the manner of a pendulum on the end of a leaf spring 72. The natural oscillation rate of the mass 70 on the spring 72 may be that of the paced heart rate. The lower end of the spring 72 is joint with a magnetic armature 75 received between the poles 76 and 77 of a permanent magnet 78.

The lower end of the armature is retained in a V-shaped recess 79 by the magnetic attraction and is correspondingly formed with a knife or V-edge 80 to provide a pivotal movement. The poles 76 and 77 are spaced apart so that the armature 75 can assume either one of two stable positions, as shown by the full lines and broken lines. In one position, the flux is induced through the armature in one direction while in the other position it is induced in the opposite direction.

Since the pendulum formed by the mass 70 and spring 72 oscillates in resonance with the sinus rate of the heart, the bending moment of the spring 72 lifts the armature 75 from one pole face whereupon it abruptly moves to the opposite pole face, resulting in a sudden reversal of the flux and inducing an electric current in the surrounding coil 82. The coil output may be applied to the storage device 63, as described in connection with FIG. 8. FIG. 11 is similar to FIG. 10 except that the mass 70' and the spring 72' are connected to stress a piezoelectric crystal 85. In this embodiment, the periodic rate of the mass and spring may be substantially greater than that of the heart, to produce a "ringing" effect with each beat.

Certain of the teachings and advantages of the present invention may be used to improve the performance of existing pacemakers which presently use endocardinal electrodes. The body Pacemaker 10 may be modified for this purpose to perform the function of the electrodes only and an arrangement for this purpose is illustrated at 100 in FIG. 12. In this case, the cartridge body 112 is made similarly to the body 12 except that it does not contain any pulsing circuitry or power source, but merely comprises means for making electrical contact. Thus, the body 112 may conveniently be made to a smaller length and/or diameter than that which has previously been described. The outer surface of the body 112 thus comprises one of the electrodes, while stimulating electrode 132 may be made and supported on a ceramic pedestal spaced from the body 112 in the manner which has been described in connection with the electrode 32 of FIG. 3.

The electrode assembly 100 will be connected by flexible leads to a conventional remote pacer by means of a flexible electrical conduit or lead 122. The lead 122 may be a coaxial conductive cable, which has one of its leads connected to the case or body 112 and the other connected to the electrode 132. The assembly 100 may be used with remote pacers which employ a single electrode lead or a pair of leads. Where a single lead is used, it would be connected inside the body 112 to the electrode 132.

The electrode assembly of this invention is provided with a somewhat modified form of attachment comprising a pair of generally axially extending retaining wires 115 and 116. The forward ends of the wires are attached or secured to the body 12. The wires extend rearwardly and outwardly, and are movable between a retracted position in which the wires lie adjacent to the outer surface of the body, to a spread apart position, substantially as shown.

The general technique of inserting and implanting the electrode assembly 100 does not differ substantially from that described in connection with the pacemaker 10. The torque tube 25 and the sheath 27 may be used, with the rod 22 removed. The cylindrical conductive end 28 would be received partially over the body 112 with the attaching wires 115 and 116 collapsed and retained within end 28. The electrical lead 122 is threaded through the hollow torque tube 25.

It would be expected that the electrode assembly would be inserted well into the apex of the ventricle cavity accompanied by some stretching of the heart muscle. The torque tube 25 could be employed to provide axial forces as well as rotational alignment. The sheath 27 would then be retracted exposing the ends of the attachment wires 115 and 116, and when the axial force is released the ends of the wires would tend to imbed themselves within the heart muscle. If necessary, some pull could be placed on the lead 122 to complete the attachment, and then the catheter may be extracted leaving the electrode assembly 100 in place.

The electrode assembly 100 provides to a remote Pacemaker certain of the advantages of the present invention. Principally, the electrodes, which are formed as integral and discrete surface portions of the assembly, are not prone to dislodgement, movement, penetration or breakage. Further, they define regions of stimulation which are spaced from the region of attachment, as in the case of the Pacemaker 10, and thus remain free of the adverse affects of fibrosis.

It is accordingly seen that this invention provides a novel self-contained biological stimulator, which is particularly adapted for use as a Pacemaker, and an electrode assembly useful with existing Pacemakers. It is intended for long-term treatment of partial or complete A-V block. Synchronous pacing may be used, as desired, and the circuit can be modified as known in the art for demand pacing. For synchronous pacing of devices of the types of FIGS. 3, 10 or 11, a short sensing or trigger electrode wire may extend axially from the rear wall 24' of the body 12b through the tricuspid valve into the right atrium to pick up the atrium pulse as a control signal for the circuit 30. For demand pacing, the surface electrode 32 may be used to pick up the ventricle pulse and suppress the trigger circuit in the manner taught for example by Keller U.S. Pat. No. 3,431,912 or Greatbatch U.S. Pat. No. 3,478,746. The physical size of the capsules which form the bodies is sufficiently small to permit long-term treatment, such as in the case of a child. The apparatus and method of the attachment and implanting is one which results in minimum discomfort to the patient. In the event of failure, the size of the Pacemaker is sufficiently small to make it feasible to simply leave it in place and to insert

a new one, although intervenous removal by catheter also is possible.

While the forms of apparatus herein described constitute preferred embodiments of the invention, it is to be understood that the invention is not limited to these precise forms of apparatus, and that changes may be made therein without departing from the scope of the invention.

What is claimed is:

1. A stimulator device for insertion in a living body and having particular advantage for intracardiac use comprising a structure having a body form for transvenous or transarterial insertion, electrode means on the surface of said body form for contact with a portion of the living body to be stimulated by said electrode means, and means mounted to project outwardly of and peripherally of said body form including anchor portions locating in a position displaced from said electrode means and providing means for engaging in portions of said living body to establish said electrode means in a required position of use, said electrode means having in connection therewith means to energize the same once said body form is located in its required position of use.

2. A stimulator device as in claim 1 wherein said means to energize said electrode means includes a power source positioning in a location remote from said body form.

3. A stimulator device as in claim 1 wherein said means to energize said electrode means includes a power source embodied within said body form.

4. A stimulator device as in claim 1 wherein spaced surface portions of said body form define separate electrode means.

5. A structure as in claim 1 wherein said anchor portions are defined b wire like segments connected with and biased to normally project outwardly from said body form to facilitate the establishment of a connection thereof with said living body in an area displaced from said electrode means.

6. A stimulator device as in claim 1 wherein said electrode means have a fixed positioning in respect to said body form and comprise at least two electrodes, and said body form includes insulator means separating said electrodes.

7. A stimulator device as in claim 1 characterized by said body form being a unitized structure having means for guiding the same for transvenous or transarterial insertion.

FIG-1

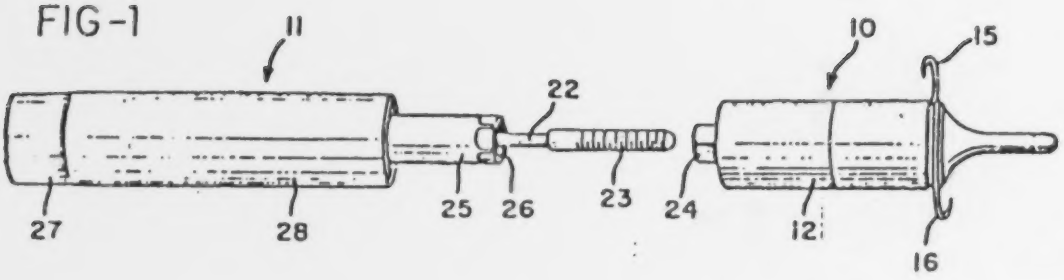


FIG-2

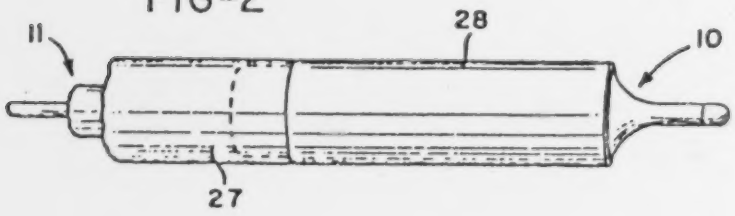


FIG-3

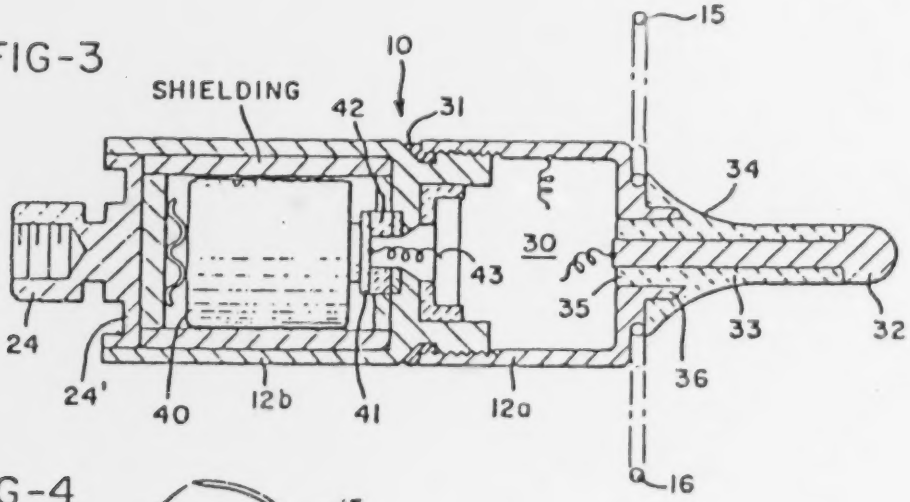
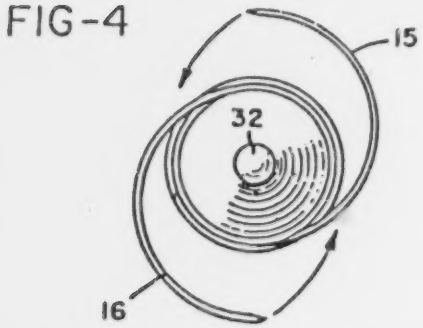


FIG-4



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BY
Marschal, Bibel, French & Bugg
ATTORNEYS

Ex.-15

FIG-5A

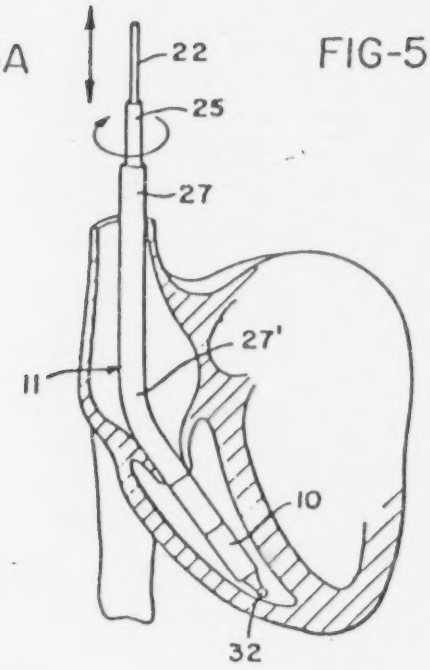


FIG-5B

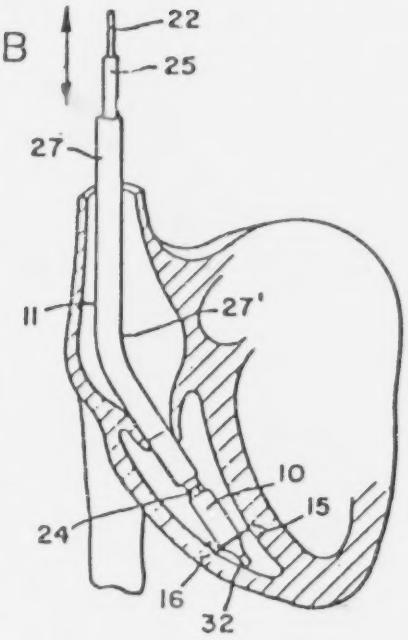


FIG-5C

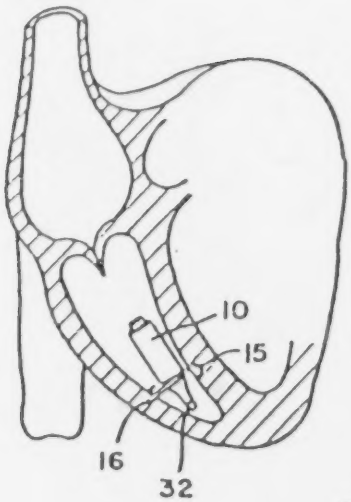


FIG-6

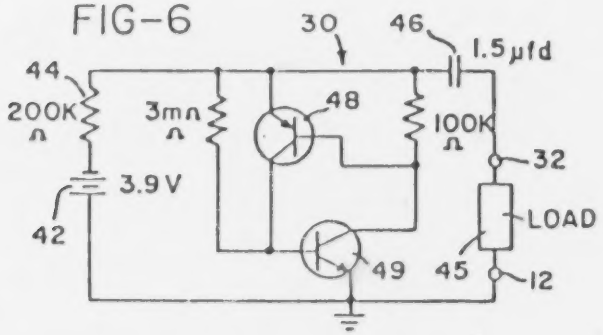
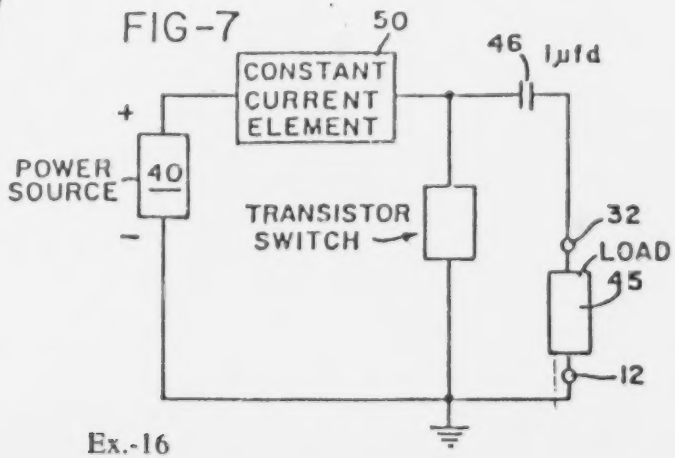


FIG-7



Ex.-16

FIG-8

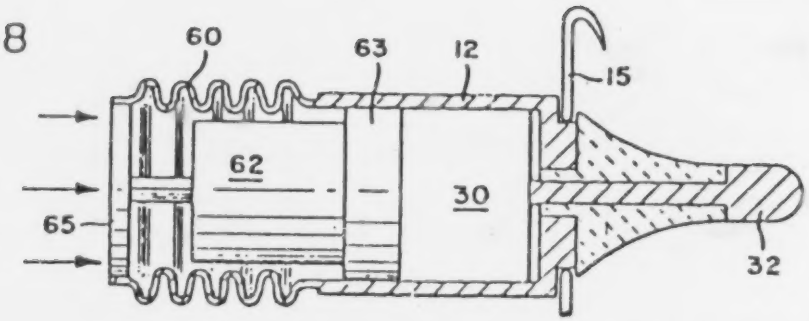


FIG-9

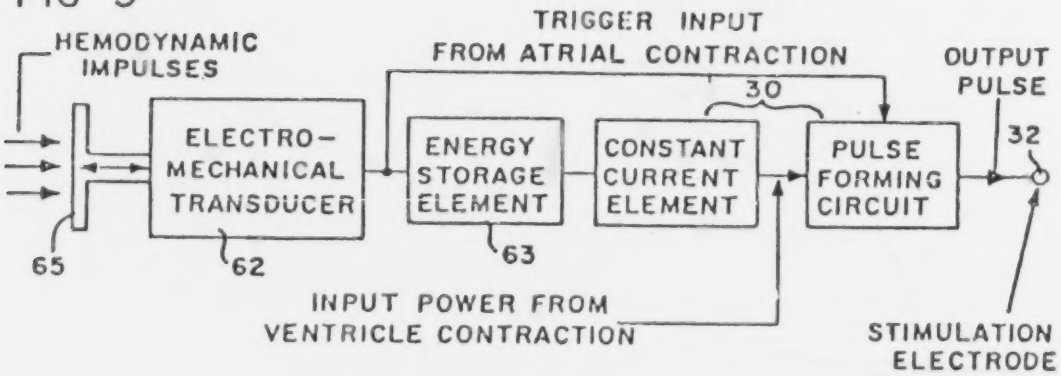


FIG-10

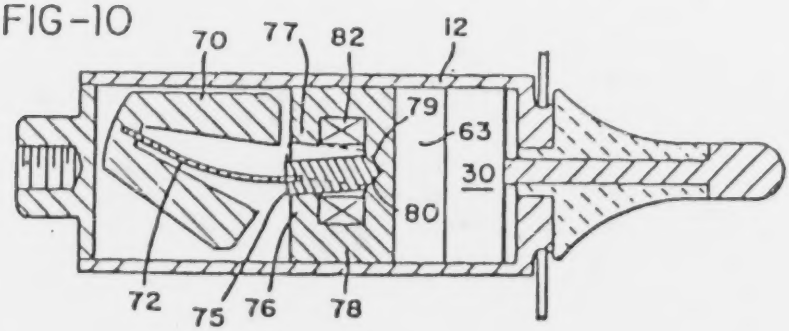
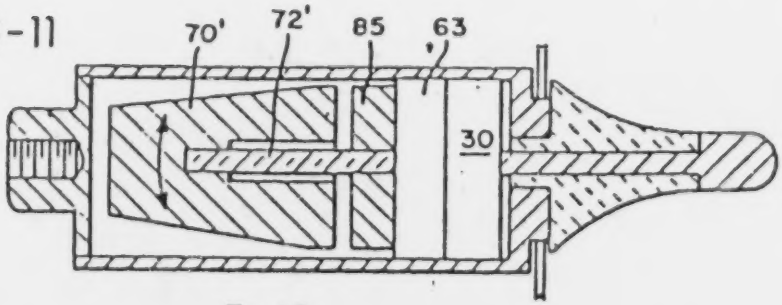
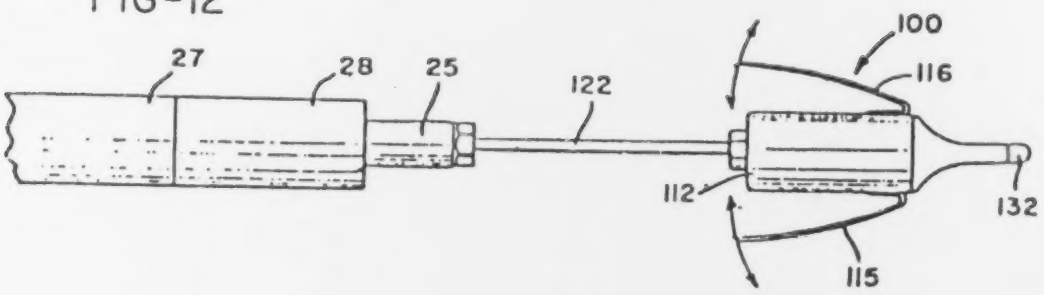


FIG-11



Ex.-17

FIG-12



UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,835,864 128 Dated September 17, 1974

Inventor(s) Ned S. Rasor and Joseph W. Spickler

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Col. 5, line 6, "activity" has been corrected to read -- cavity --;

line 16, "preferred" has been corrected to read -- preferably --.

Col. 6, line 32, "radiosotope" has been corrected to read -- radioisotope --.

Signed and sealed this 18th day of February 1975.

(SEAL)
Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents
and Trademarks

NEW PACEMAKER ELECTRODES

Max Schaldach

For the long-term treatment of a large variety of disturbances in the conduction system of the heart, the electric cardiac pacemaker has proved superior to any other therapy. The only disadvantage today is its relatively short time of operation, determined by the limited capacity of the commonly used zinc-mercury oxide elements. An increased life time can be achieved if either new power sources with a better energy density to volume ratio or new stimulation electrodes are available which prevent the waste of energy due to polarization effects. It is the object of this paper to describe a new pacemaker electrode with respect to low power consumption in the long-term therapy of patients. Primary attention will be focused on the electrochemical problems of the solid-heart tissue interface. In addition, technical details of a new atrial sensing catheter electrode will be discussed, which has small wire hooks at its tip for attaching it to the endocardial surface.

MATERIALS AND METHODS

The behaviour of metals employed as stimulation electrodes is of considerable interest in experimental medicine and biomedical engineering, particularly in such applications as cardiac pacemakers. In most commercial pacemaker electrodes the material used so far is either platinum-iridium or elgiloy, an alloy containing cobalt, nickel, molybdenum, manganese, iron, carbon, and berillium. These electrodes are either sutured into the muscle of the heart or inserted into the right ventricle by means of a transvenous catheter. The energy required to stimulate the heart depends on the electrode and is usually 1-5 μJ when the pacemaker electrode is first implanted. The electrical behavior of the tissue around the stimulation electrode and the effect of the electrode upon it can be evaluated from the stimulation threshold and the operational value of the electrode circuit. The term threshold means the smallest amount of electrical energy which will produce consistent cardiac contraction with the electrode system used, when the stimulation impulse falls past the absolute and the relative refractory period of the heart.

In Figure 1 a typical threshold curve is shown using an elgiloy catheter electrode connected to the output circuit described in the drawing. The myocardial threshold increases during the first weeks of implantation caused by interstitial edema and the growth of connecting tissue around the catheter tip. In metallic electrodes the stimulation energy cannot be substantially reduced by changing the surface area of the electrode or the impulse duration.

Since a high current density vs. a high electric field strength at a small electrode is required locally to stimulate the cardiac muscle, several polarization voltages are developed with the consequence that most of the delivered energy from the pacemaker circuit is wasted in the electrode electrolyte interface. This is particularly important in the case of implanted pacemakers since their life time is determined by the energy stored in their batteries. Considerable improvement of the life time could be achieved if the stimulation system worked more economically.

The electrochemical reactions in the electrode interface are very complex and involve possible electrode corrosion, gas evolution, and oxydation vs. reduction of metabolites with potentially toxic effects on a long-term basis[1].

It is recognized that ideally the processes taking place at stimulation electrode surfaces probably should be solely those involving motion of electric charges without any irreversible chemical reaction taking place. To demonstrate the electrochemical aspects in Figure 2, the potential model of a metal electrode in contact with the endocardium is shown. The potential distribution in the interface gives a simplified overlook of the electrochemical behavior under steady state conditions. The potential depends on the distance from the electrode surface and is made up of the drop in the rigid Helmholtz-double layer, the space charge region, and the membrane potential. The diffusion potential represents the electrical changes between the excitable membrane and the electrode surface. Thus, the rise in stimulation threshold can be expressed in this portion of the potential distribution, so that an increase in the thickness of the connective tissue layer results in a threshold rise. The electrical performance can be described in the equivalent circuit. Because of the non-linearity of electrochemical processes, the value of each component is a function not only of the time but also of the applied electrode voltage V_E[2].

To demonstrate the electrochemical polarization of metal pacemaker electrodes in Figure 3, the current density vs. electrode potential curves for platinum and elgiloy are shown. During polarization the change of the electrode potential results as well in the Helmholtz-potential as in the potential drop of the diffusion layer. This results in an energy loss of charging and recharging the Helmholtz capacity. When the applied electrode potential rises above a critical value (Figure 4), ions discharge, chemical reactions take place, current flows across the interface, and the electrical energy is now irreversibly wasted. As a result of this current flow, the field strength necessary for triggering the next excitable cardiac membrane breaks down. The stimulation occurs only

From the Department für Biomedizinische Technik der Friedrich Alexander Universität, Erlangen-Nürnberg

Trans. Amer. Soc. Artif. Int. Organs, 1971

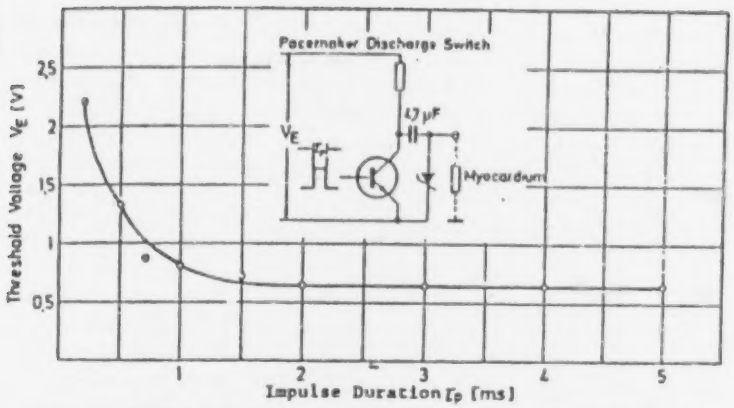


Figure 1. Threshold voltage vs. impulse duration for intracardiac electrodes in humans (initial stimulation in the right ventricular apex).

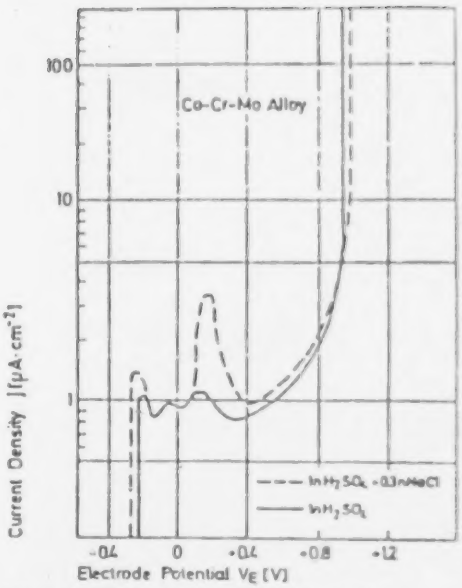


Figure 3. Anodic polarisation of a Co-Cr-Mo stimulation electrode.

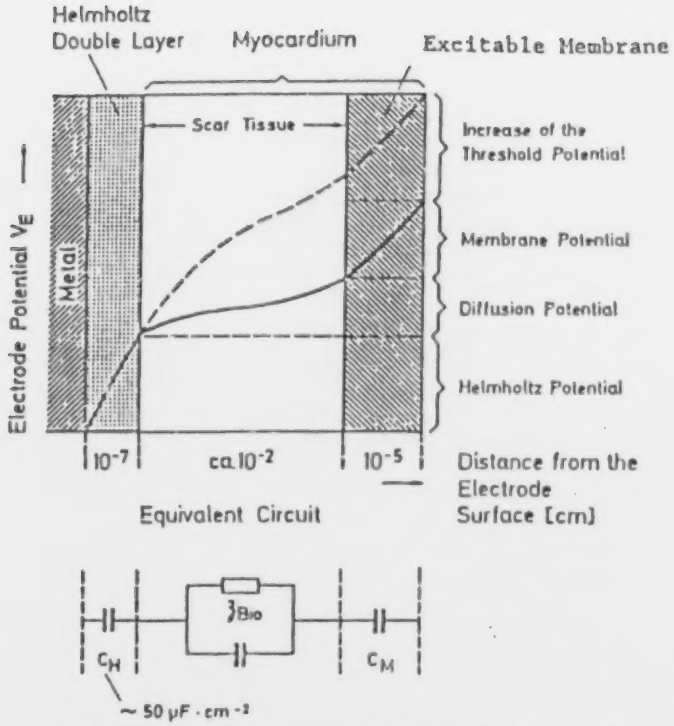


Figure 2. Potential distribution and electrical properties of the metal/ myocardium interface.

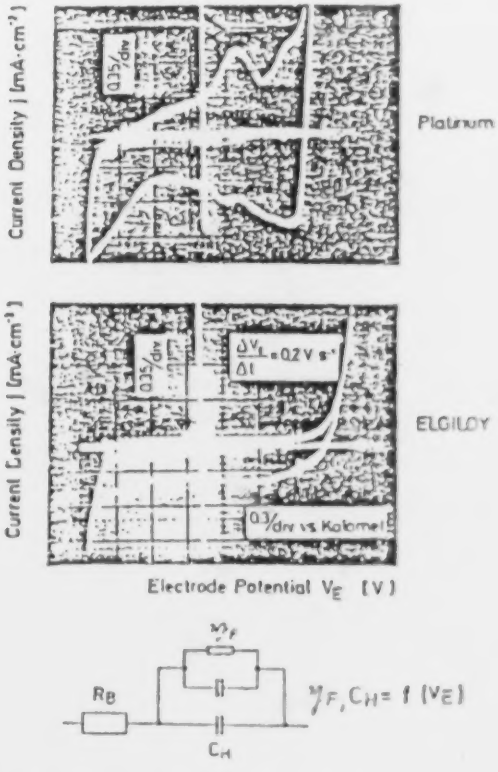


Figure 4. Pt- and elgiloy-stimulation electrodes in physiological saline solution.

as the result of a change in ion concentrations due to a current flow near the excitable membrane. The Faraday-impedance, F, now determines the electrochemical behavior.

The DCD electrode. One way to avoid the wastage of energy due to polarization effects has been discussed by Parsonnet[3] using a so called "Differential Current Density Electrode." In this system there is a low current density at the metal to avoid polarization and a high current density at the contact to the endocardium to produce a significant fieldstrength to activate responsible cells. As a result, stimulation thresholds are found whose energy is 1/10 of that achievable with conventional metal electrodes. Figure 5 shows the dimensional drawing of the DCD electrode. The electrochemical behavior is demonstrated in the current density vs. electrode potential curve of Figure 6. The shape is determined by a current-limiting resistor, R_H, in series, as described in the equivalent circuit below. The value of the internal resistor ranges from 2-4 Kohms. The only disadvantages of this method are difficulties in stable fixation of the electrode, and electrochemical instability due to the development of fibrotic tissue within the chamber.

The dielectric pacemaker electrode. To prevent electrochemical reactions, a thin dielectric layer is used on the surface of a metallic electrode tip (Figure 7). The passage of an electrical pulse through the interface of such a coated electrode involves only a change of the charge distribution in the metal and ions in the electrolyte. Charge transport is now possible through the oxide-film. That means no faradaic reactions can occur, and as a consequence, such a system avoids electrochemical reactions such as electrode corrosion, gas evolution, and reactions with metabolites. The potential model of this electrode and its equivalent electrical circuit is shown in Figure 8. The equivalent circuit of this electrode must be completed by an additional in-series capacitor of the same magnitude as the Helmholtz-capacitance. The current density vs. electrode potential curve in Figure 9 demonstrates the electrochemical behavior of this dielectric pacemaker electrode. In the electrode potential range below 1 V vs. calomel, the electrode acts as a pure capacitor. This results in the fact that a part of the delivered pulse energy is also lost due to the fact that the charge stored in the capacitor during a pulse is not utilized for stimulation.

The electrodes consist basically of a metal tip which is coated by a thin dielectric layer of electrochemically deposited tantalum oxide. A helical elgiloy wire is used for connection to the pacemaker pulse generator. Silastic medical grade tubing has so far been used as encapsulating material. In Figure 10 the dielectric pacemaker electrode for transvenous stimulation is demonstrated in comparison to the DCD, the Elema-platinum, and the Biotronik-elgiloy electrode.

RESULTS

Preliminary studies with various models of dielectric stimulation electrodes in animals confirmed the in vitro results that stimulation thresholds are 3 times lower than those measured with standard metal electrodes. Therefore, it appeared that the transvenous model was acceptable for clinical trial. The electrode was inserted through the cephalic vein into the right ventricular apex. In 5 patients the electrodes were attached to external pacemakers and stimulation thresholds were tested until the electrodes were removed and replaced with conventional elgiloy-electrode catheters. The preliminary results in clinical application confirmed that no electrochemical reactions occur. The required threshold energy is 1/3 of the energy that is required in the use of metal electrodes of similar geometric size. No change in the capacity of the dielectric layer could be observed.

As an advantage, in comparison to the DCD electrode, the dielectric pacemaker electrode allows more safety for satisfactory contact to the myocardium. The animal experiments, as well as the clinical results, suggest the feasibility of this new pacemaker electrode. The low energy requirement may improve pacemaker technology by reducing the number of batteries and thus the pacemaker size, or by increasing pacemaker life time with the present number of batteries.

The atrial sensing electrode. The atrial synchronous pacing acts as an artificial conduction system. It is the most physiologically responsive mode of pacing today. Although this method was introduced relatively early in the evolution of cardiac pacing[4], in practice, the percentage is about 5% of all cases treated, which contrasts with the hemodynamic advantage. Judging from these results, the implantation procedure seems to be compared with transvenous pacing. The first and still most widely used thoracotomy must be recognized as an excellent method for stable atrial synchronous pacing. However, this approach is more difficult, traumatic to the myocardium, and entails a high risk, particularly for aged patients. Therefore, in the past years, an attempt was made to avoid the thoracotomy technique. In 1966, Carlens and Lagergren[5-6], published the method of fixing the atrial sensing electrode transmediastinally by means of a mediastinoscope. This method was only successful if the electrode tip was placed well against the posterior atrial wall and does not move during the early period of healing.

Another method, the retrosternal approach, is described by Bruck[7] and Dittrich[8]. Through a subxiphoid incision, the right ventricle is approached, and both the ventricular stimulating and the atrial sensing electrodes are sutured to the right ventricle and to the right atrium. This method offers no significant advantages over the thoracotomy.

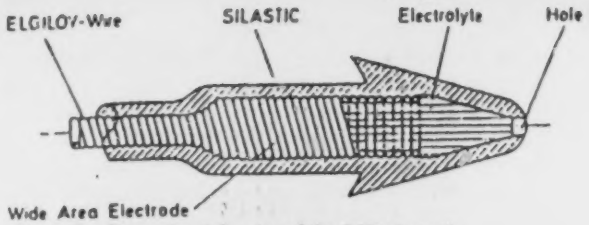


Figure 5. Dimensional drawing of the DCD electrode.

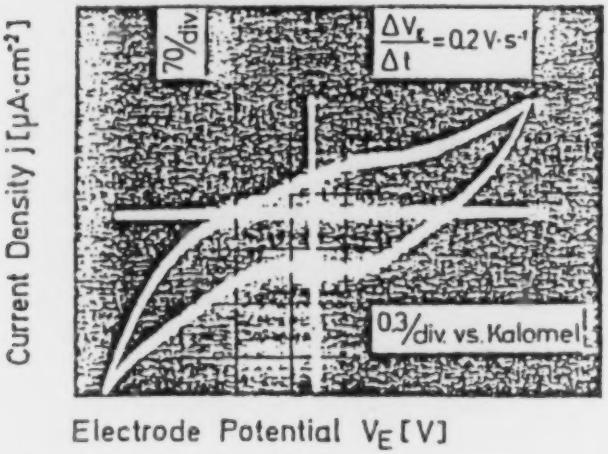


Figure 6. Current density vs. electrode potential curve.

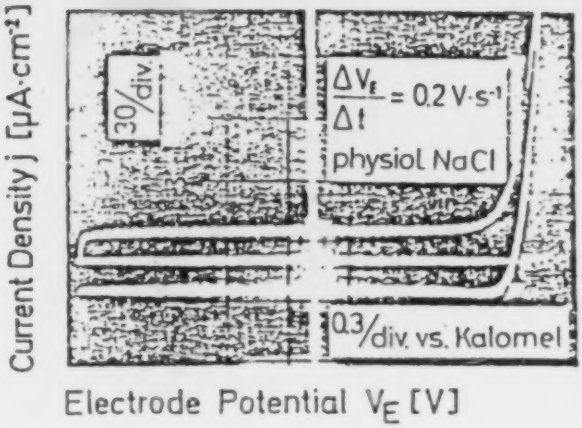


Figure 9. Current density vs. electrode potential curve.

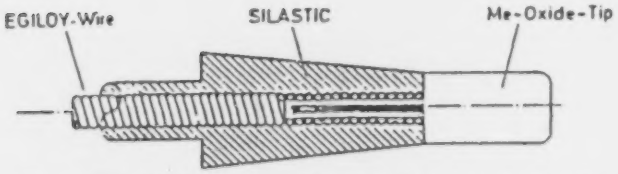


Figure 7. A thin dielectric layer is used on the surface of a metallic electrode tip.

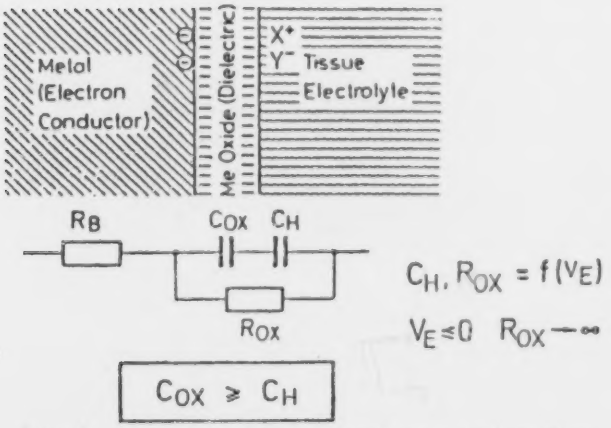


Figure 8. Potential model of electrode and its electrical equivalent circuit.

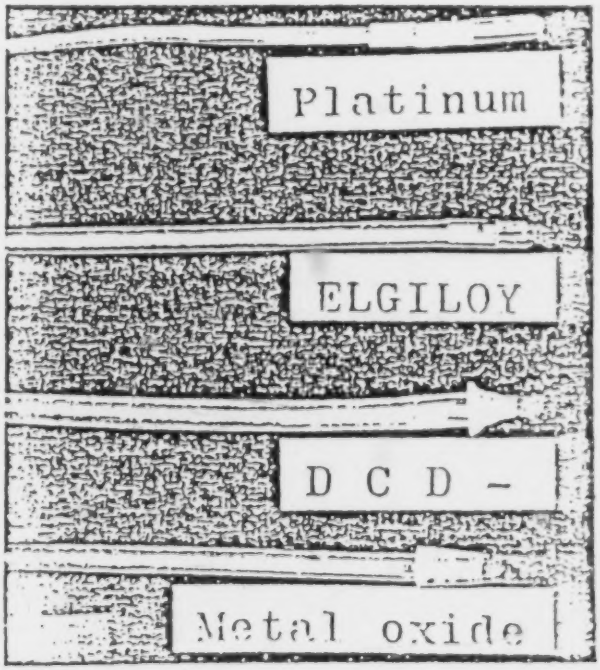


Figure 10. The dielectric pacemaker electrode for transvenous stimulation is compared to the DCD, the Elema-platinum, and the Biotronik-elgiloy electrode.

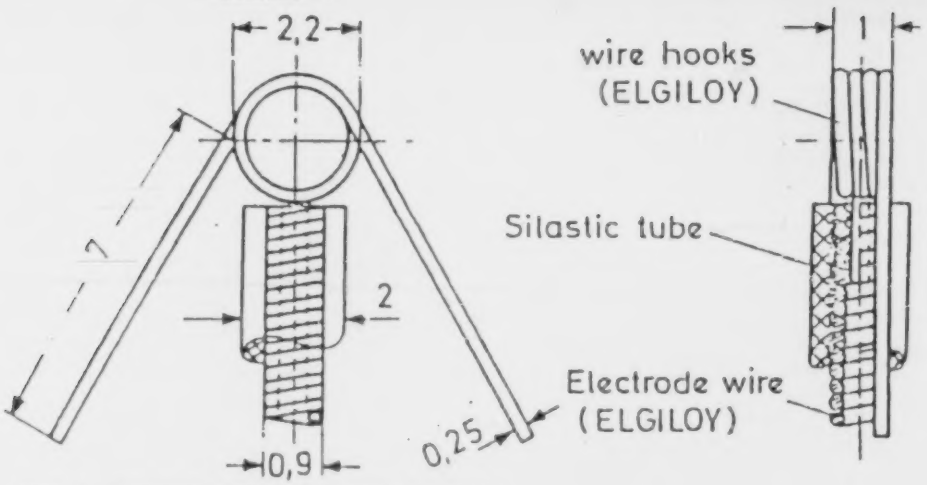


Figure 11. Dimensional drawing of the sensing catheter tip.

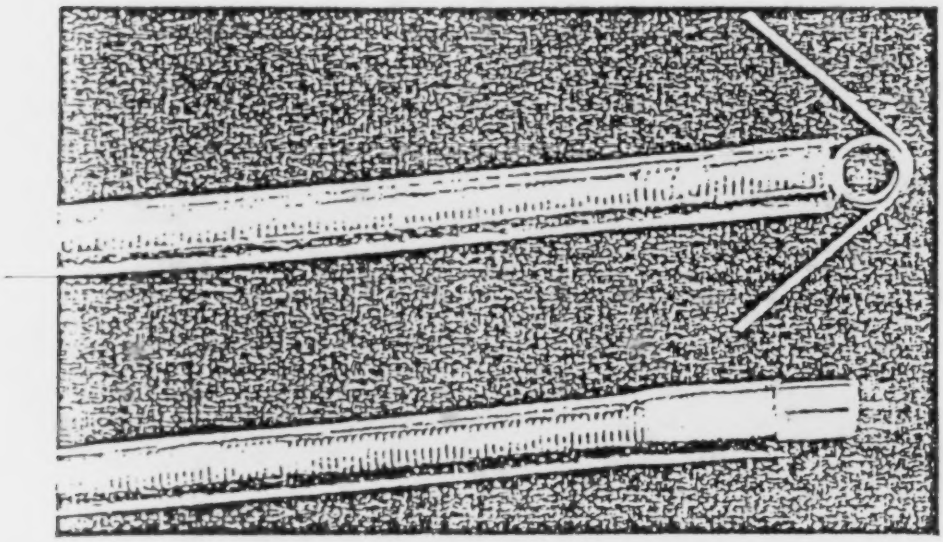


Figure 12. The atrial and ventricular electrode.

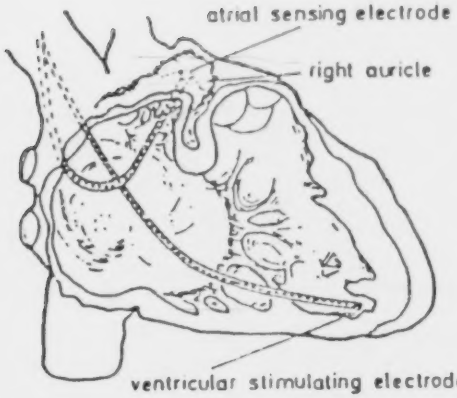


Figure 13. Atrial synchronous pacing, transvenous placement.

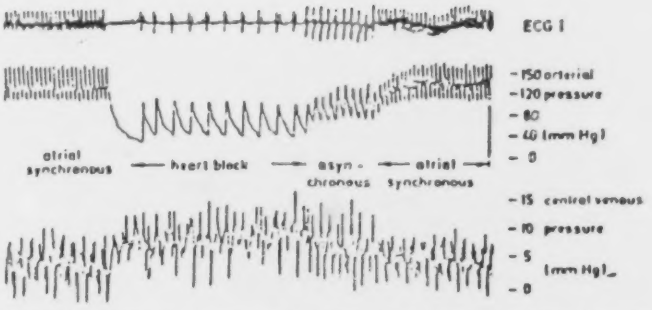


Figure 14. Increase in mean systolic pressure and decrease in central venous pressure.

In addition, the use of atrial sensing catheters has already been reported[9,10]. Straight atrial electrodes were used with high input-sensitive pacemakers, but stable synchronization could not be achieved[9-11]. Better results were obtained by the application of curved atrial electrodes[10]. When these electrodes are properly positioned with the right atrium, a more stable synchronization than with the straight electrodes was found[9,12]. However, this method as well as our own experience[13] with a precurved electrode, where the sensing and stimulation electrode are fixed by a platinum double ring and placed in the atrium, do not satisfy the requirements for safe synchronous operation. Bruck[7] suggests the possibility of utilizing the transseptal puncture technique for fixing a transvenous sensing electrode into the area of the fossa ovalis. However, no clinical experience is available as yet.

This paper will present an intraatrial catheter technique for the stable fixation of the sensing electrode tip into the atrial appendage[14,15]. To maintain permanent contact with the atrial endocardium, the electrode tip is provided with fine wire hooks so that it can be firmly anchored between the trabeculae of the right auricle.

Figure 11 shows the dimensional drawing of the sensing catheter tip. A picture of both the atrial and the ventricular electrode is shown in Figure 12. Both electrodes are made of an elgiloy helical coil insulated by a silicone rubber tube terminating in a cylindrical tip, or a wire hook, made of the same elgiloy material. To ensure high flexibility, the wire hooks are turned in a relief loop. This design provides sufficient safety in cases of electrode removal via a guiding tube. The stiffness of the electrode can be varied by introducing an additional guiding wire into the lumen of the helical coil.

The application of this technique for atrial synchronous pacing requires a precurved guiding catheter as protection against injury to the veins, atrial wall, and tricuspid valve. The catheter is made of radiopaque teflon tubing. Any vein of proper diameter at the root of the neck or in the pectoral region can be used for entry into the venous system. In most cases, the right external jugular and the cephalic vein are satisfactory or, if these are of inadequate diameter, the internal jugular vein can be used. Once the position of the guiding tube is correct, the atrial sensing electrode is advanced through the tube into the appendage up to the point where the end of the wire hooks are still inside. Further advancement of the electrode will release the wire hooks to anchor in the trabeculae of the right atrial appendage, where P-wave potentials normally exceed 5 mV. The placement is conventional in every regard. The final position of both electrodes in the heart is demonstrated in Figure 13.

Clinical experience. Atrial synchronous pacing applied according to the aforementioned method was clinically applied in 68 patients; ages ranged from 12 to 70 yr with a mean of 60 yr. Arteriosclerosis obliterans has been quoted as the main cause of total AV-block in the presented case material. Much less common as etiologic factors are congenital cardiac defects, infections, and degenerative diseases. The majority of treated patients were between 60-70 yr, and implantation via thoracotomy of the atrial synchronous system is not acceptable for this group. The transvenous approach seems to be the only method combining the advantage of using transvenous pacing and atrial synchronizing. The clinical results gained since August 1968 demonstrate the benefit of this method. The long-term results have shown the hemodynamic importance of the atrial contribution to cardiac output especially in those cases with disease. The improvement in cardiac function is demonstrated by the increase in mean systolic pressure and decrease in central venous pressure as indicated in Figure 14.

SUMMARY

The main clinical application of stimulating electrodes today is for use in cardiac pacemakers. The electrode materials exclusively used so far are noble metal alloys (e.g. Pt/Ir) or stainless steels (e.g. elgiloy, an alloy containing Co, Cr, Ni, Mo, Mn, Fe, C, and Be). The problems besetting these metallic electrodes are 2 kinds:

1. Since a high current density and a small electrode is required locally to stimulate the cardiac muscle, several polarization voltages are developed with the consequence that most of the stimulating energy is wasted at the electrode electrolyte interface. This is particularly important in the case of implanted pacemakers since their life time is given by the energy stored in their batteries. Considerable improvement in longevity could be achieved if the electrodes worked more economically.
2. The electrochemical reactions in the electrode interface are very complex and involve possible electrode corrosion, gas evolution, and oxydation vs. reduction of metabolites with potentially toxic effects on a long term basis.

It is recognized that ideally the processes taking place at physiological electrode surfaces probably should be solely those involving motion of electric charges without any irreversible chemical reaction taking place. The application of such a non-polarizing electrode was reported by Parsonnet, who achieved a reduction of the stimulation energy down to 1/10 of the energy that is required in the application of metal electrodes. The disadvantage of this electrode was found in its instability during long-term operation.

To avoid this disadvantage a purely capacitive electrode was developed and tested in vitro and in vivo. This electrode consists of a metal which is covered by a thin dielectric oxide film. The application of an electrical impulse through the interface involves only a change of the charge distribution and the required fieldstrength

for triggering the next excitable membrane in the conduction system of the heart. The application of catheter electrodes with oxide layers in animal experiments as in clinical tests confirmed that no electrochemical reactions like corrosion, gas evolution, and reaction with metabolites occur. Only a thin fibrotic layer could be observed and the capacity always remains stable. The required energy to stimulate the heart is 1/3 of the energy that is required in the application of metal electrodes of similar geometric size.

In addition, a new electrode catheter is demonstrated which has small wire hooks at its tip for fixing it to the endocardial surface. This method has been successfully used in 68 patients for fixation of the pick-up electrode in the right auricle of the heart for atrial synchronous pacing.

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P Wave Synchronous Pacing Using Anchored Atrial Electrode Implanted Without Thoracotomy

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A new technique for the transvenous implantation of a specially designed atrial sensing electrode is described. In combination with a ventricular stimulating electrode and an atrial-controlled pacemaker, the method enables synchronization of atrial with ventricular activity. The atrial sensing electrode is put into the right atrial appendage through a preshaped radiopaque Teflon applicator catheter. Two hooks on the electrode tip provide for safe and secure anchoring of the electrode tip to trabeculae of the atrial appendage. The technique has been used for synchronous P wave pacing in 12 patients with complete atrioventricular block, most of them suffering from Adam-Stokes attacks. Three additional patients with sinoatrial block were treated by means of anchored atrial electrodes. Observation periods of up to 39 months showed no dislocation of any of the anchored atrial electrodes, and performance in all patients was faultless.

Of the different methods for implanting electrical pacemakers, the transvenous-endocardial technique has come to the fore in recent years. This approach is superior to the use of myocardial and epicardial electrodes since the surgical risk is considerably reduced, inasmuch as the pacemaker is implanted under local anesthesia without need for either thoracotomy or pericardiotomy. The method thus far has been used with pacemakers equipped with a single ventricular electrode, as in fixed-rate and ventricular-controlled pacing.

Atrial-controlled pacemakers, with 1 sensing electrode in the atrium and 1 ventricular electrode, have so far been placed transthoracically. The need for major surgery may explain the relatively infrequent use of atrial synchronous pacemakers in most hospitals, although their use in comparison with fixed-rate pacemakers provides physiologic coordination between atrial and ventricular activity and adjustment of the heart rate to the imposed load.

Gilmore et al.[1] and Samet et al.[2] reported that with synchronized pacing the cardiac output increased beyond that achieved through asynchronous ventricular pacing by about 20 percent of the initial value. Therefore, atrial-controlled pacemakers seem to be desirable in most patients. Their use should not be limited to younger, still working patients, since they are of particular value to aged patients with established cardiac damage. The obvious advantages of atrial synchronous pacemaking justify past efforts to develop techniques for atrial detector electrode implantation by which thoracotomy can be avoided. In 1965, Carlens et al.[3] reported a method of transmediastinal implantation of the atrial sensing electrode by means of a mediastinoscope. In 1967, Schaldach et al.[4] recommended a transvenous-endocardial approach to the heart, the control electrode being attached by means of platinum rings to a common ventricular electrode. Smyth et al.[5] implanted hook-shaped prestressed atrial elec-

From the Centre of Cardiovascular Research, Charité Hospitals, Humboldt University of Berlin, German Democratic Republic. Manuscript received July 9, 1971, accepted October 1, 1971.

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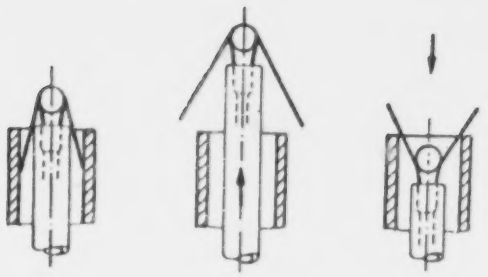

Figure 1. Nonoperatively implanted transvenous anchored atrial electrode: tip construction, introduction, fixation and means for removal.

trodes. Similar procedures have been described by Dodinot et al.,[6] Faivre et al.,[7] Rodewald et al.,[8] Kramer and Moss,[9] Kastor et al.[10] and Castillo et al.[11]

The foregoing techniques have not had wide clinical use, since none provides means for stable fixation of the sensing electrode in the atrium. Bruck[12] suggested that atrial sensing electrodes could be applied by transseptal puncture technique, but clinical experience with this technique has not yet been reported. Our group has devised, and first used in man in August 1968, a technique enabling safe fixation in the right atrium of a transvenously introduced atrial sensing electrode.

Method

The tip of the sensing electrode is shown in Figure 1. The feed unit of the electrode catheter consists of an Elgiloy spiral. The electrode tip is formed by 2 fine wire hooks of the same material, each ending in a relieving loop, thus providing the necessary flexibility to the hooks. The insulating material used for the catheter electrode is silicone rubber. The sensing electrode has at its tip 2 fine hooks or barbs, each 7 mm long. These are used to anchor the tip of the electrode in the trabeculae of the right atrial appendage.

The "fishhook" electrode catheter is introduced through the exposed external jugular vein, which is ligated peripherally, and, over the properly positioned anchored electrode. The internal jugular vein may be used when necessary, in which case the vein is closed and the electrode stabilized by means of a single purse-string suture.

Needed instruments include a guide wire (0.9 mm by 150 cm), a radiopaque, conically tipped polyethylene catheter (8F, 80 cm), and an applicator tube of radiopaque Teflon® (Cook, Bloomington, Indiana, TRT, 12F, 45 cm). The applicator is a pre-curved metal rod with a hook-shaped tip (Fig. 2).

The implantation is performed as follows: First, the guide wire is passed during fluoroscopy by way of the open vein into the right atrium, and the 8F catheter and outermost 12F applicator tube are passed over it. When the wire and inner catheter are removed, the end of the Teflon applicator, now resting in the right atrium, regains its hook shape and can then be manipulated by rotation into the atrial appendage (under fluoroscopic control), and its position checked by the injection of contrast medium. The

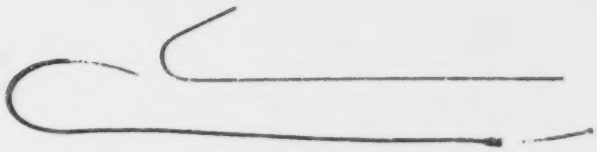

Figure 2. Applicator catheter. **Above,** curved wire for preshaping catheter. **Below,** curved applicator catheter with coaxial inner polyethylene catheter.

Figure 3. Atrial sensing electrode and ventricular stimulation catheter placed without thoracotomy.

barbed electrode, lubricated by silicone oil and stiffened by a mandrel, is introduced through the lumen of the applicator. During its introduction, 2 barbs or hooks on the end of the electrode are pressed together. When the tip of the electrode leaves the applicator, these hooks are freed to unfold within the appendage and anchor its trabecular system. The applicator is carefully withdrawn over the electrode catheter, slight forward pressure on the electrode protecting its connection in the appendage. The stiffening wire mandrel is then withdrawn. If the electrode barbs are inadvertently detached from the atrial appendage during mandrel removal, reanchoring is done by repositioning the curved applicator tube.

Should an unanchored sensing electrode be swept into the ventricle, it can easily be drawn close to the applicator in the atrium. If an electrode is to be exchanged for another, it can easily be removed through the applicator since the hook spreading mechanism is reversible.

The ventricular stimulation catheter electrode, put in through a cephalic vein, is routinely inserted before the sensing electrode for reasons of safety (Fig. 3). The procedure is performed with the patient heparinized. Connection to the infraclavicular-implanted, atrial-controlled pacemaker is made after measurement of the atrial activity potential and a performance check of synchronous stimulation.

Trigger sensitivity of the Biotronik-IVP-pacer is set at 0.5 mv, a level appropriate to the signal picked up by the atrial sensing fishhook electrode. Despite the relatively high input sensitivity, interference is not significantly increased, since the pacemaker is encapsulated in a case of austenitic chromium-nickel-molybdenum steel, which acts as the indifferent electrode in the stimulation circuit.

The signals from the atrial sensing electrode after amplification are used to trigger a monostable multivibrator.

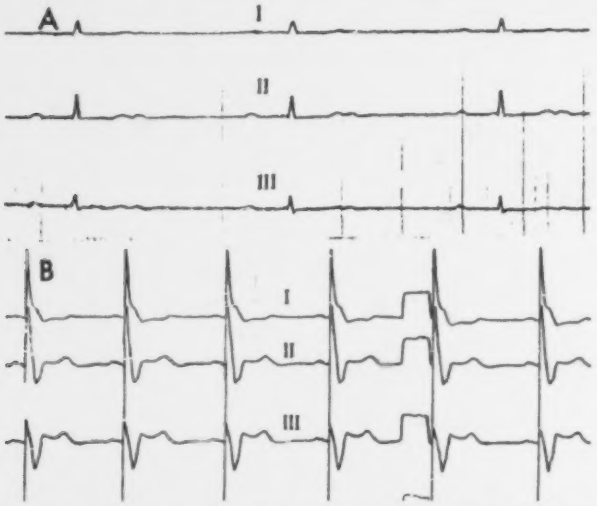

Figure 4. 2:1 A-V block in a 54 year old woman. Before (A) and 2 years after (B) pervenous electrode implantation of atrial-triggered pacemaker.

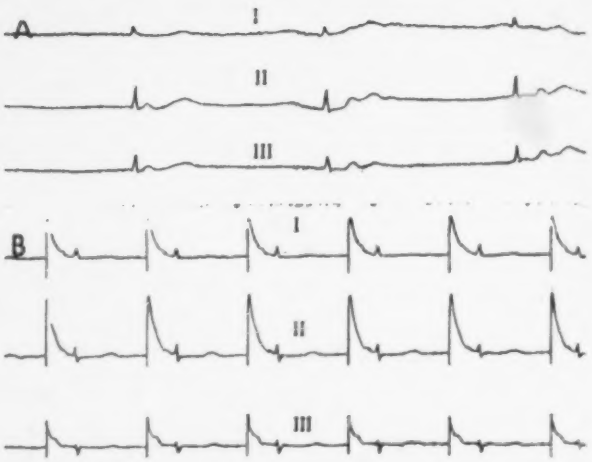

Figure 5. Extreme sinus bradycardia in a 62 year old man. Before (A) and 6 months after (B) pervenous implantation of an anchored atrial electrode coupled to a fixed-rate pacemaker.

An "atrioventricular" delay of 120 msec precedes activation of the output circuit and the production of a stimulating impulse at the ventricular electrode. The pacemakers (Biotronic IVP-44 and IVP-54) used in the procedure are basically designed to provide atrial synchronous operation within a frequency range of 70 to 140 beats/min. Automatic blocks built into the electronic circuit maintain the ventricular rate within this range, thus preventing inadequate or excessive ventricular rates. To this end, each stimulating impulse is followed by a period during which all signals from the amplifier will be suppressed by the timing circuit. This pacemaker refractory period, set at 400 msec, determines the maximal synchronous rate. If the upper limit of 140/min is exceeded, a frequency divider built into the pacemaker circuit provides a properly phased 2:1 ventricular stimulation signal. The maximal rate for a 2:1 block is also limited by the refractory period of the pacemaker, and a shorter refractory period is required if a higher maximal rate is desired. In the event of atrial rates below the lower limit of 70/min, malfunction or fracture of the atrial pickup lead, or arrhythmias such as atrial flutter and fibrillation, the timing circuit provides automatic nonsynchronous ventricular stimuli at 70/min, preventing either block or externally induced "pacemaker tachycardia."

Results

Atrial synchronous systems have so far been implanted by this method in 12 patients (age range 17 to 72 years) with atrioventricular (A-V) block at the Centre of Cardiovascular Research of the Charité Hospital in East Berlin (Fig. 4). In addition, 3 patients with sinoatrial (S-A) block or extreme sinus brachycardia (Fig. 5) were treated by the introduction of an atrial electrode coupled to the output of a fixed-rate pacer system. The follow-up period has been more than 30 months in 2 patients, from 21 to 30 months in 3, from 11 to 20 months in 3, from 6 to 10 months in 4, and from 1 to 5 months in 5. The maximal follow-up period thus far has been 39 months. In no instance was an atrial electrode dislocated.

Transient sensing failure, occasionally evident immediately after implantation, but in all cases corrected after 2 to 5 days, is attributed to traumatic edema or hematoma at the site of implantation. In this series, the long-term performance of these transvenously implanted, anchored atrial electrodes has been faultless.

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Ex.-29

Feb. 3, 1970 E. M. FOUNTAIN 3,492,996

VENTRICULO-ATRIAL SHUNT

Filed Feb. 3, 1966 2 Sheets-Sheet 1

Fig. 1

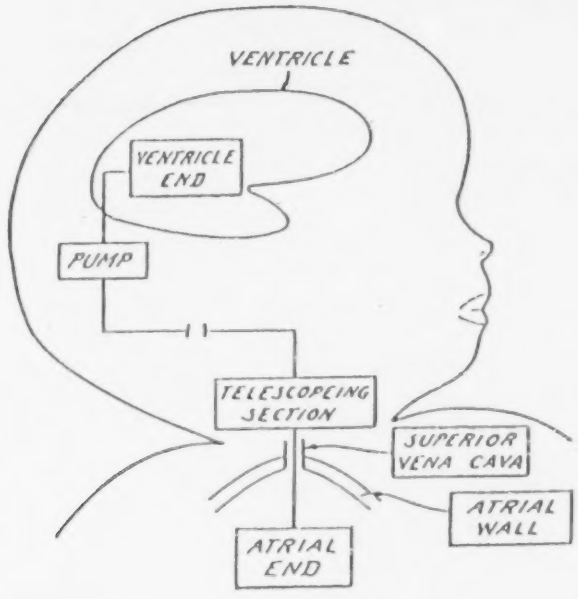


Fig. 2

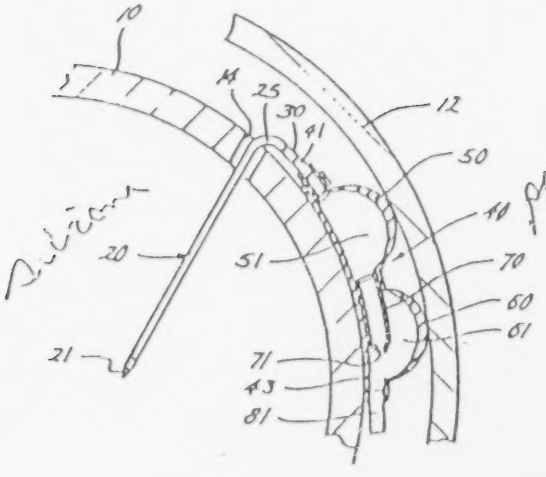
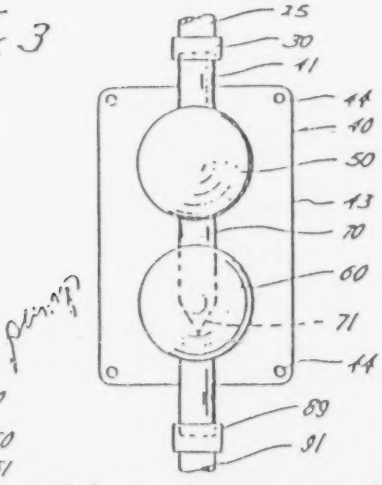


Fig. 3



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PLAINTIFF'S EXHIBIT
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Civ. 3-83-251
NO. 127

Feb. 3, 1970 E. M. FOUNTAIN 3,492,996

VENTRICULO-ATRIAL SHUNT

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Fig. 4

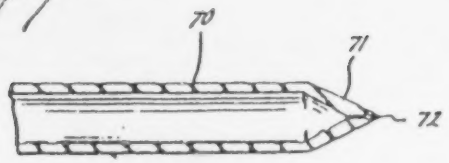
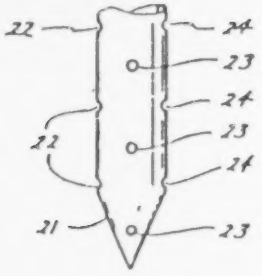


Fig. 5



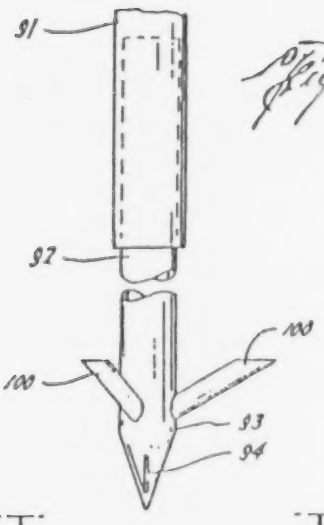


Fig. 6

Fig. 7

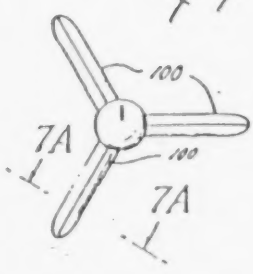


Fig. 7A

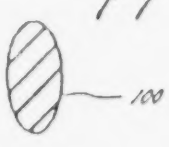
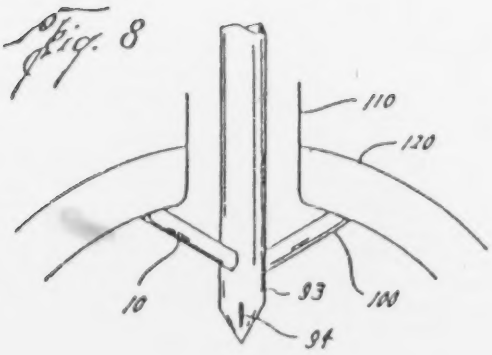


Fig. 8



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Ex.-31

United States Patent Office 3,492,996 Patented Feb. 3, 1970

3,492,996

VENTRICULO-ATRIAL SHUNT

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Filed Feb. 9, 1966, Ser. No. 526,294
Int. Cl. A61m 27/00
U.S. Cl. 128—350 5 Claims

ABSTRACT OF THE DISCLOSURE

This application describes a surgically implantable device for relieving fluid pressure on the brain. The device comprises a ventricular conduit adapted for introduction into the brain, a pumping device attached to the ventricular conduit and an outlet conduit attached to the pumping device and adapted to be inserted into the atrium. The pumping device is a substantially flat, flexible plate adapted to overlie the skull and has a pair of bubble-shaped chambers positioned thereon and adapted for finger manipulation to provide pumping action to clear the conduits of obstructions. The outlet end of the device is provided with flexible wings adapted to hold the device within the atrium or center it in the vein entering the atrium in the event that the end is pulled from the atrium. One-way valves are provided to prevent blood back-flow into the brain.

This invention concerns a new and improved device for treating hydrocephalics, i.e., those persons, usually infants or children being afflicted with, as commonly described, water on the brain. Also, this condition may exist in certain adults whose circulation or absorption of cerebro-spinal fluid is impaired by various inflammatory or tumor processes.

More particularly this invention contemplates a means whereby secreted cerebro-spinal fluid may be directed into the blood stream and thereby throughout the normal course of the body system.

Normally, cerebro-spinal fluid is secreted by the choroid plexus and ventricular lining within the cranial ventricles. Such fluid may enter the vascular system by a route approximated by passing out of the lateral ventricles, through the third ventricle, out the formaina of Magendie and Lushka, into the cisterna magna whenceforth into the subarrachnoid spaces and absorbed by the blood system. Such fluids may be absorbed and recycled several times daily.

With hydro-cephalics the cerebro-spinal fluid is unable to be absorbed adequately. Thus, on continued secretion, pressure increases greatly, causing the ventricles to swell or expand. As expansion occurs the wall material becomes thinned. Expansion occurs at the expense of brain substance, and fluids. Thus, in essence, the head becomes a box, closed save for incoming material.

Previous attempts to relieve the extreme pressures and return such cerebro-spinal fluid to the circulation have been fraught with numerous difficulties. For example, flushing of such earlier devices has proved difficult or frequently impossible, and the cardiac portion has not been permitted to lengthen with normal growth of the patient.

Thus, this invention has as its purpose the permitting of relieving of increased intra-cranial pressure by reintroducing cerebro-spinal fluid into the vascular system.

A further object is the provision of a device which may longitudinally extend so as to permit continuous utilization in a growing human.

Yet another object is the provision of means whereby the ventricular end may be flushed.

These and still other objects and benefits will become

apparent on considering the following appended description and drawings in which:

FIGURE 1 is a schematic representation of the relative positioning of the shunt ventricular and atrial ends, pump and telescoping portions;

FIGURE 2 is a section through a skull showing positioning of the pump mechanism and ventricular shunt relative thereto;

FIGURE 3 is an elevation of the pump mechanisms and connections thereto;

FIGURE 4 is a section through one end of the ventricular-atrial conduit.

FIGURE 5 is an enlarged elevation of the end of the ventricular portion of the shunt;

FIGURE 6 is an elevation of the telescoping portion and atrial end of the shunt;

FIGURE 7 is an end view of the shunt atrial end, taken along lines 6—6 of FIGURE 5, and

FIGURE 7a is a section taken along lines 7a—7a of FIGURE 7; and

FIGURE 8 is a section showing the placement of the shunt atrial end relative to the superior vena cava.

Looking first at FIG. 1, for an overall view of the operation of the device, the venticular end of a shunt device is positioned within a cranial ventricle. Said shunt ventricular end is connected to a pump mechanism, later described, which may be inserted under the scalp. Said pump leads subcutaneously to a telescoping section of a conduit, and thereafter to the atrial end of a shunt, which atrial end is positioned within the atrium of the heart. Said atrial end may be inserted in the jugular vein, through an incision therein, pass therethrough and be prevented from being dislodged from the atrium through or to the superior vena cava by reason of projections near the terminal end of said atrial end.

Look now at FIGURE 2 which depicts the pump and the ventricular portion of the shunt. Said shunt refers to the conduits from either end of the pump. The skull of a person is indicated by the numeral 10, and the scalp by 12. An aperture is shown by 14, which may be a burr hole or even a perforator opening which is substantially smaller.

A ventricular shunt 20, which consists generally of thin flexible hollow conduit, preferably of silicone rubber, has one end 21 inserted within a cranial ventricle, which ventricle is under excessive pressure due to the buildup of cerebro-spinal fluid. Said one end possesses a number of perforations, with the perforations closely bunched and arranged preferably with each grouping being rotated 90° from the adjacent grouping and vertically spaced therefrom, as indicated by groups 22, 23, and 24, respectively (FIG. 5).

The other end 25 may pass through said skull opening 14, to be joined by connector 30, to the ventricular end 41, of pump 40. Said connector may be made of polyethylene, silicone rubber, nylon or other suitable material, and would have an aperture therethrough, communicating both with the ventricular shunt and with conduit-like end 41 of said pump.

The pump 40, actually would perform as a dual pumping mechanism in the following manner. A flexible base portion 43 possesses suture holes 44 for affixing said base to periosteum of skull 10. Spaced toward opposite ends of said base are hemisphere-like bubble portions 50 and 60, which define chambers 51 and 61, respectively, between said bubbles and said base. Actually, said bubbles serve as individual pumps in that each may be compressed so as to eject fluids present within their respective cavities outwardly thereof. Said conduit end 41 is shown to communicate both with ventricular pump 50 and with ventricular shunt 20, by virtue of connector 30. Also, pump 50 communicates with atrial pump 60 by virtue

of ventricular-atrial conduit 70. The atrial end 71 of said conduit terminates within chamber 61 of pump 60. Said atrial end may have a slit 72 formed therein which, in the absence of sufficient pressure against the adjacent walls, would normally be closed. Thus said conduit and slit would function as a one way valve preventing fluids from returning from chamber 61 to chamber 51, i.e., from the atrial shunt through the ventricular shunt thence back into the ventricle.

Atrial pump 60 is linked by conduit 81, by virtue of connector 89, similar to member 30, to the upper member 91 of atrial shunt 90 and communicates therewith by virtue of said conduit, connector and shunt being cylindrically conformed.

Said upper portion 91 will have a larger internal diameter than, and telescopingly receive lower portion 92, both portions consisting of tubing, preferably, again of silicone rubber. The telescoping portion of member 92 may be prevented from sticking by properly coating members 91 and 92.

FIGURES 6, 7, 7a and 8 depict said lower portion of the atrial shunt. The lower or atrial end 93 of member 92, includes one or more slits 94, again functioning as a one-way valve. Positioned closely adjacent thereto are a plurality of slightly upwardly directed, wing-like projections 100. Preferably there are three such projections spaced radially 120 degrees apart around the periphery of the end 93 of the atrial shunt.

It woud be beneficial for the device to be substantially treated with a barium-containing substance so that on X-rays being taken, the exact location of all the parts thereof may be determined.

In actual use, ventricular shunt 20 would be inserted through cranial perforation 14 into a cranial ventricle, the brain being under considerable internal pressure. Cerebrospinal fluid would pass through apertures 22, 23 and 24 into the interior of ventricular shunt 20, therethrough, into cavity 51 of pump 50, thence through conduit 70, out one-way valve 72 into chamber 61 of pump 60. Said pump 60 may, by pressing down on the adjacent scalp, and thereby compressing the pump 60, cause such fluids to pass downwardly through conduit 81, connector 89 and into the upper member 91 of atrial shunt 90, from where it would pass through the atrial end 92 of said atrial shunt, out one-way valve 94, into the atrium from which location said fluids may eventually be absorbed into the blood system. Pressure on pump 50 would normally have the same effect. Normally, in the absence of obstructions or occlusions, said pumps would not need to be utilized, in that said fluids would follow the described route without needing assistance.

Normally the linkage from the pumping mechanism to the atrial end of the atrial shunt may be inserted underneath the skin. The lower member 92 of said atrial shunt 90 would be inserted within the jugular vein and course through the superior vena cava, pass downwardly therethrough into the atrium. By virtue of projections 100, which may readily bend upwardly, so as to permit downward passage through said superior vena cava 110, said atrial end of said atrial shunt, may not return upwardly through vein 110, in that said projections 100 would rest adjacent atrial wall 120. This would tend to prevent scarring of the superior vena cava wall as well as thrombosis which might occur should member 92 be pulled back within vein 110, and be bound to the wall thereof by a membrane or clot. Even should said atrial end be pulled back within vein 110, said projections 100 would keep said atrial end centered in the stream of blood flowing through said vein, keeping the device operative. Positioning of atrial end 93 is permitted, even in growing children by virtue of the telescoping nature of members 91 and 92.

A further advantage permitted by this device is the flushing of the ventricular end of the shunt. Inasmuch as conduit 70 has a one-way valve 72 at one end, if pump 60 is depressed so as to close said valve, then pressure on valve 50 will tend to force fluids contained in cavity 51 and the ventricular shunt 20 back through the perforations in end 21. Thus, stoppages resulting from occlusion of the ventricular end, perhaps bits of brain matter, debris or clumped leukocytes may be overcome.

Although only a single embodiment of this invention has been described it should be apparent that numerous modifications would be possible by one skilled in the art without departing from the spirit of the invention. The scope of which is intended to be limited only by the following appended claims.

What is claimed is:

1. In a surgically implantable device for relieving excess pressure within the brain comprising a first fluid conduit means adapted for introduction of at least a portion thereof into a brain ventricle, a second fluid conduit means for fluid outlet, a pumping device positioned between said first and second conduit means and interconnecting the same, and a one-way valve positioned in the system to prevent fluid back-flow into the brain, the improvement which comprises:

said pumping device comprising a pair of hemisphere-like, bubble-shaped, thin-walled resilient chamber portions positioned in spaced relationship on a substantially flat, flexible base member, said base member defining the lower boundary of each of said chamber portions, each portion being adjacent to one of said conduits and intercommunicating therewith,

said bubble-shaped chamber portions being interconnected by third conduit means including a one-way valve whereby when said pumping device is manipulated, the first conduit can be flushed to clear it of obstructions.

2. The improvement as defined in claim 1 wherein said third conduit means terminates within said chamber adjacent to said second conduit means.

3. The improvement as defined in claim 2 wherein said one-way valve in said third conduit means is provided with a slit which acts as a one-way valve.

4. The improvement as defined in claim 1 wherein: the terminal portion of said second conduit means, which is opposite the end to which said pumping device is connected, is provided with a plurality of wing-like, flexible projections adapted to rest against blood vessel walls of the patient and center the conduit in the flow of the blood.

5. The improvement as defined in claim 1 wherein: said flexible base member is provided with means for attachment of sutures thereto.

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United States Patent

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[11] 3,635,223

[45] Jan. 18, 1972

[54] EMBOLECTOMY CATHETER

[72] Inventor: Charles H. Kliernan, Brooklyn, N.Y.

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[22] Filed: Dec. 2, 1969

[21] Appl. No.: 881,363

[52] U.S. Cl. 128/348, 128/356

[51] Int. Cl. A61m 25/00, A61b 17/22

[58] Field of Search ..... 128/348-351, 344, 128/303, 325, 246, DIG. 9, 2, 356, 328

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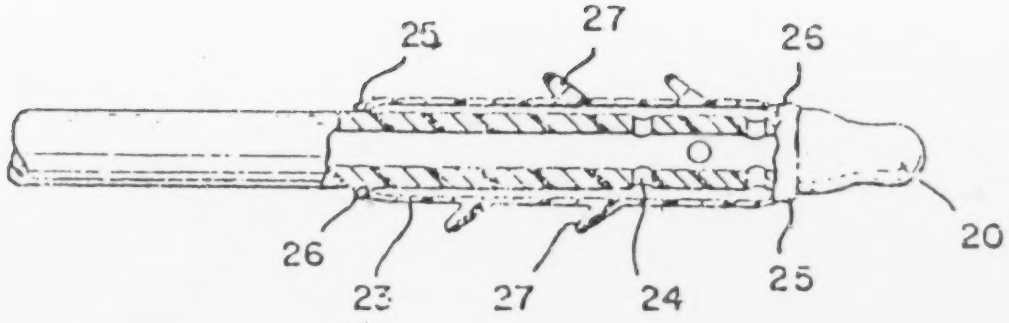
Primary Examiner—Dalton L. Truluck

Attorney—W. Saxton Seward

[57] ABSTRACT

Apparatus for extracting emboli comprising a cannula, preferably guidable, adapted to be projected through a body passage (e.g., vein or artery) to a point adjacent the embolus to be removed, together with a catheter adapted to be passed through the cannula and having a distal end provided with an inflatable balloon the surface of which has rearwardly angled protrusions designed to engage an embolus into which the catheter end has been projected and to convey the captured embolus into the cannula as the catheter is withdrawn therein

7 Claims, 7 Drawing Figures



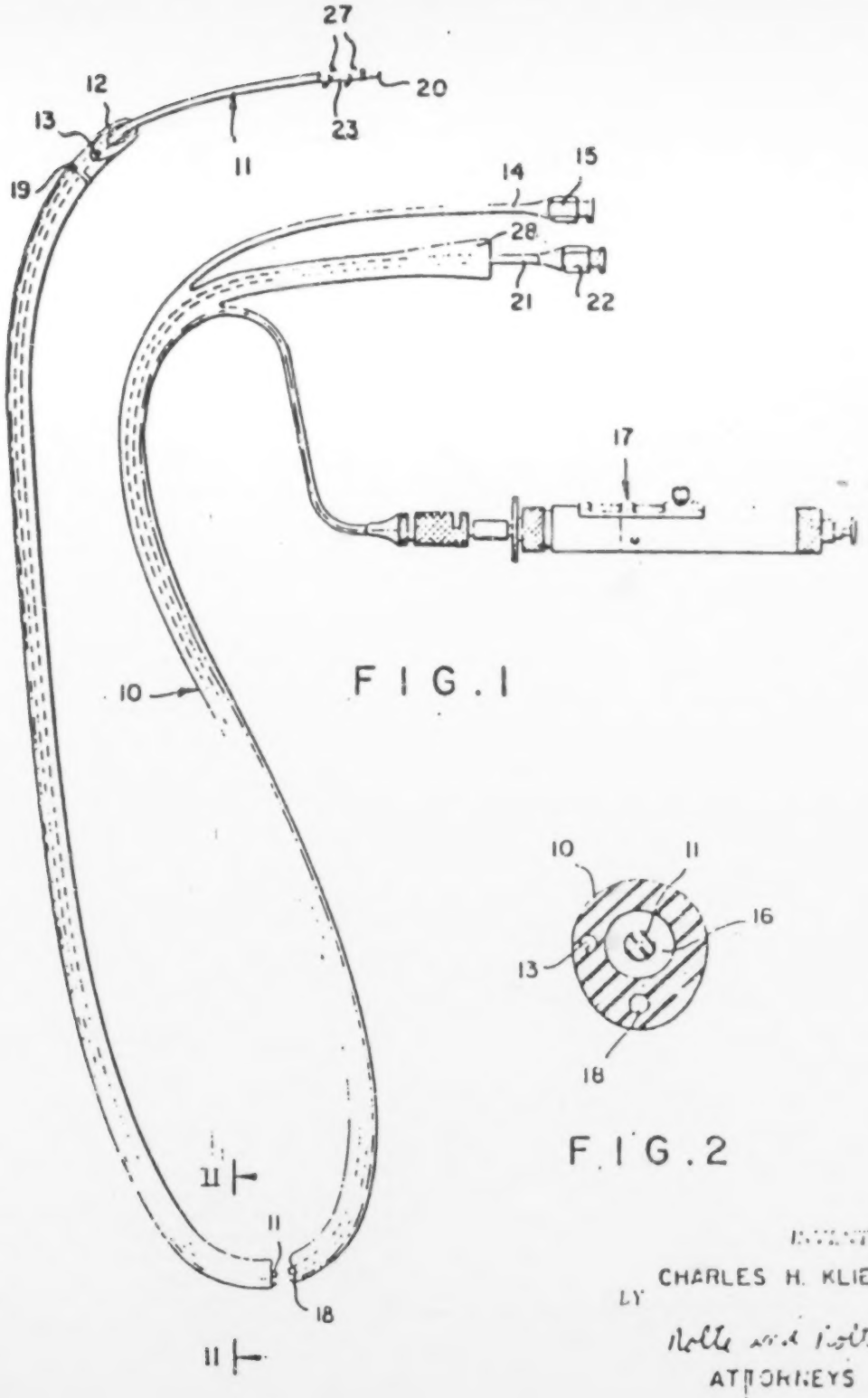


FIG. 1

FIG. 2

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FIG. 3

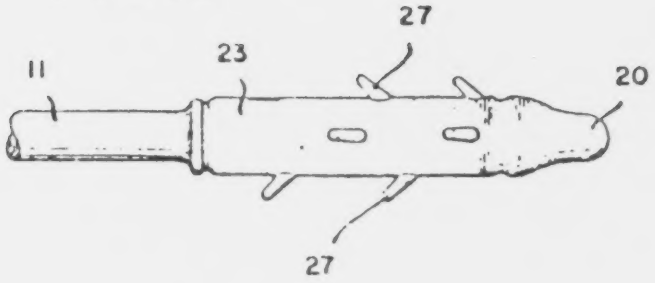

FIG. 4

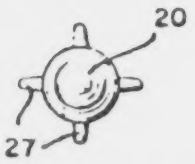

FIG. 5

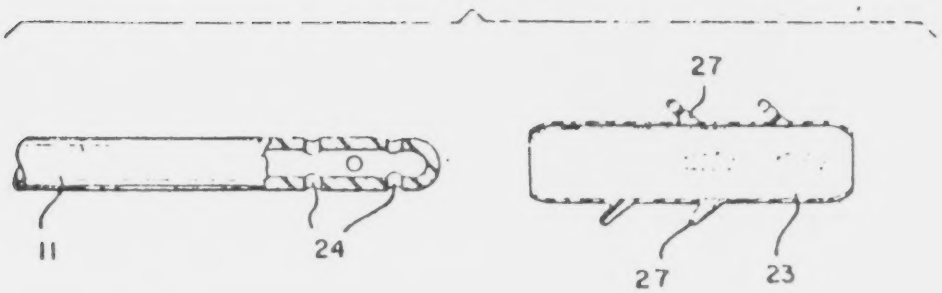

FIG. 6

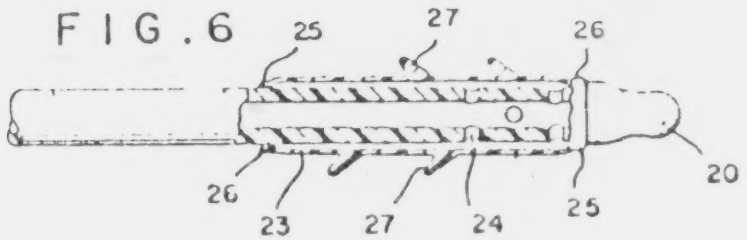

FIG. 7

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EMBOLECTOMY CATHETER

BACKGROUND OF THE INVENTION

A definite need exists for a catheter unit to remove pulmonary emboli. A pulmonary embolus is a blood clot that has formed in some area of the body and traveled via the venous system into the pulmonary arteries. The site of origin of these emboli is usually the veins of the leg, secondary to conditions such as thrombophlebitis. If a massive pulmonary embolus occurs, the mortality rate is high. The only method available at this time to remove these clots is by a direct surgical attack on the pulmonary artery. Even then the mortality rate is very high. The present catheter unit's purpose is to avoid the need for surgery and permit the emboli to be removed via a peripheral vein such as the femoral vein. Other uses have been developed for one or both parts of the catheter unit to be described. Each use will be described in detail.

A practical embodiment of the invention is shown in the accompanying drawing wherein:

FIG. 1 represents an elevation of the outer guided cannula with the extraction catheter inserted therethrough, parts being broken away;

FIG. 2 represents a cross section on the line II—II of FIG. 1;

FIG. 3 represents an elevation of the distal tip of the extraction catheter on an enlarged scale;

FIG. 4 represents an end view of the tip shown in FIG. 3;

FIG. 5 represents detailed axial sections of the catheter, adjacent its distal tip, and of the balloon prior to assembly thereof;

FIG. 6 represents the same parts as in FIG. 5, assembled; and

FIG. 7 represents an elevation of a mandrel on which the balloon may conveniently be formed.

Referring to the drawings, the apparatus is shown as comprising two parts, the outer guided cannula 10 and the inner catheter 11, constituting the emboli-extracting instrument.

The outer cannula 10, which may be 80 cm. to 100 cm. in length, is preferably 20 F. in diameter with a substantially circular lumen having a diameter on the order of 0.164 inch, its distal end 12 being opened at an angle to provide an actual opening larger than the lumen. The cannula 10 is formed with a main lumen 16 and a small second lumen 13, open at the distal end (e.g., in the short end of the bevel) and provided at its tubular proximal end 14 with a fitting 15, to receive a syringe tip for the injection of dye, for instance. The cannula 10 is flared proximally, as indicated at 28, to permit insertion of the catheter 11, as described below; it is also provided with a deflecting device comprising the operating handle 17 and a fine wire 18 secured at its distal end 19 near the distal end 12 of the cannula, by which means said cannula end can be deflected, in a known manner, and guided to desired locations. The handle 17 may be of the type shown in Muller U.S. Pat. No. 3,425,740, or an adaptation thereof. The material of the cannula 10 is suitably a radiopaque polyvinyl chloride or equivalent nonreactive, nontoxic and atraumatic material, with or without wire reinforcement.

The inner catheter 11, 20 cm. to 25 cm. longer than the cannula 10 may be 3 F. to 8 F. in diameter, radiopaque and of woven Dacron or the like. Its distal tip 20 is soft, flexible and closed, and its proximal end 21 is provided with a fitting 22 to receive tip of a syringe for a purpose described below. The catheter 11 has an inflatable balloon 23 of latex, vinyl or other suitable elastomeric material mounted adjacent its distal tip, the balloon being constituted by a substantially cylindrical sleeve long enough to cover the openings 24 normally provided near the tip of such a catheter, the ends of the sleeve being tied by threads 25 and tightly secured to the surface of the catheter by said threads and by an application of a suitable adhesive 26 over the threads and adjacent edges of the sleeve.

The balloon is provided with a plurality of integrally formed "barbs" or protrusions 27, each approximately 1 mm. in length, slanted away from the tip of the catheter at angles of 30° to 60°, for instance (45° being shown), and distributed around the balloon surface at intervals preferably no greater than 90° with respect to the catheter axis. The diameter of the balloon portion, including protrusions 27, should be not appreciably greater than the inside diameter of the cannula (e.g., less than 0.164 inch) with the balloon collapsed (not inflated), to enable said portion to be passed through the cannula, as described below, without undue frictional resistance.

In using the apparatus for pulmonary embolectomy, the emboli-extracting catheter 11 is placed within the outer cannula 10, the unit is introduced into the femoral vein, and under observation with an image intensifier, is guided up through the vena cava, through the right side of the heart and out into the pulmonary artery. Dye is then injected to determine the exact location of the embolus, so that the distal end of the cannula 10 may be placed close to it. The inner catheter 11 is pushed through and past the clot, (e.g., to a position as shown in FIG. 1 with respect to the cannula 10) and then pulled back, the protrusions 27 engaging the clot and ensuring its capture and withdrawal into the cannula through the enlarged opening at the end 12. If necessary, due to the size of the vein and/or clot, the balloon 23 may be inflated by means of a syringe engaged in the fitting 22, the vinyl balloon having sufficient elasticity to permit an appreciable increase in its effective diameter. Following the first withdrawal of the catheter into the cannula, dye is again injected to determine if all the clot has been removed, and repeated projections and retractions of the catheter can be made until the clot removal is completed. The slanting arrangement of the protrusions 27 ensures that they will engage the clot only for withdrawal, emerging from the cannula relatively "clean" for each repeated pass, if more than one pass is needed. When the clot appears to have been completely captured, the entire unit is removed.

It has been found that, in many instances, the presently used Fogarty catheter is not fully effective to remove iliofemoral venous or arterial emboli. The inner emboli-extracting catheter 11 can be used (without the cannula 10) for this purpose. Its advantages reside in the soft flexible tip, the vinyl balloon with slanted protrusions, and its ability to remove clots without necessarily having to inflate the balloon in the vessel. In such an operation the catheter is introduced distally into the femoral artery or vein and advanced past the embolus, the soft flexible tip ensuring that the vessel wall will not be damaged. After the balloon has been pushed past the clot, it is withdrawn, the protrusions 27 engaging the clot and removing it. If necessary, the balloon may be inflated to the desired extent to ensure engagement with and removal of the clot. Repeated passes may be made into the femoral, deep femoral, popliteal and iliac vessels to completely remove the clot or clots. The protrusions on the balloon are rounded and sufficiently flexible to avoid damage to the vessel but are firm enough to hold onto the clot. When using the catheter 11 without the cannula 10 it is particularly convenient and desirable for the catheter to be calibrated at suitable intervals such as every 10 cm.

Instances have been reported of occlusion of the renal artery by emboli, and the only presently known procedure for saving the affected kidney is operating on the patient to remove the clot. The cannula and catheter described herein can be used to remove such clots, thus avoiding the need for surgery. In this situation, the assembled unit is passed up the femoral artery to the level of the renal artery, as located by the injection of dye. The slant-opened distal tip 21 of the cannula is approximated to the opening of the renal artery and the inner catheter 11 is then projected into the renal artery to pass, engage and remove the clot or clots as described above. The clot or clots captured with the cannula are then removed as the cannula is withdrawn.

A convenient and economical means for making the balloon 23 is illustrated in FIG. 7, where the metal (e.g., brass) mandrel 30 is shown as having a handle 31, a shank 32 and a cylindrical enlarged portion 33 tapering smoothly at both ends to the diameter of the handle, as indicated at 34. A plurality of slanting tapering holes 35 are drilled at suitable points, cor-

responding to the desired number and distribution of the projections 27. The mandrel is used by dipping in a bath of elastomeric material, maintained sufficiently liquid to flow into the holes 33, the material depositing on the mandrel to the desired thickness. After removal from the bath, the deposited material is cured in an appropriate manner, the sleeve with "barbs" on its inner surface is turned inside out, and the ends trimmed to leave a balloon as shown at the right of FIG. 5. The inside diameter of the cylindrical portion of the balloon may conveniently be slightly greater than the outside diameter of the catheter, as indicated in FIG. 6, the actual difference being on the order of 0.010 to 0.020 inch.

As used herein, "distal" refers to the leading end or direction of advancement into the body and "proximal" refers to the end or direction opposite to said distal end or direction.

What is claimed is:

1. An embolectomy catheter comprising an elongated tubular body having a closed soft flexible distal tip, at least one perforation through the wall of said tubular body adjacent said tip, inflatable sleeve of elastomeric material covering said perforation and sealed to the surface of said body distally and proximally of said perforation, and a plurality of protrusions of the same material integrally formed on said sleeve at a plurality of circumferential points, projecting laterally therefrom and slanted away from said distal tip, whereby when said tip is inserted within a blood vessel past an embolus, said slanted protrusions will engage said embolus and upon retraction of said catheter will ensure withdrawal of said embolus from the blood vessel.

2. A catheter according to claim 1 which includes a fitting on the proximal end of said body adapted to receive a syringe tip.

3. A catheter according to claim 1 in which the catheter is of a woven plastic material having dimensional stability and being at least partially radiopaque.

4. A catheter according to claim 1, in which the sleeve is sealed to the body by a circumferential tie covered by adhesive.

5. In combination, a catheter according to claim 1 and an outer cannula having at least one lumen open at both ends, the diameter of said lumen being substantially as great as the diameter of a circle passing through the outer ends of said protrusions, the length of said cannula being less than the length of the catheter, and said catheter being slidably received within in said cannula.

6. The combination of claim 5 in which the distal end of the cannula has a slanted opening, the area of which is larger than the cross-sectional area of the cannula lumen.

7. The combination of claim 5 in which the cannula is a radiopaque vinyl plastic and the catheter is at least partially radiopaque.

* * * * *

United States Patent [19]

Collett

[11] **3,717,151**

[45] **Feb. 20, 1973**

[54] FLESH PENETRATING APPARATUS

[76] Inventor: Robert M. Collett, 927 North Huntington, San Fernando, Calif. 91340

[22] Filed: March 11, 1971

[21] Appl. No.: 123,291

[52] U.S. Cl. 128/347, 128/350

[51] Int. Cl. A61b 17/34, A61m 27/00

[58] Field of Search ..... 128/242, 244, 343, 345, 347, 128/348, 350 R, 350 V, 351

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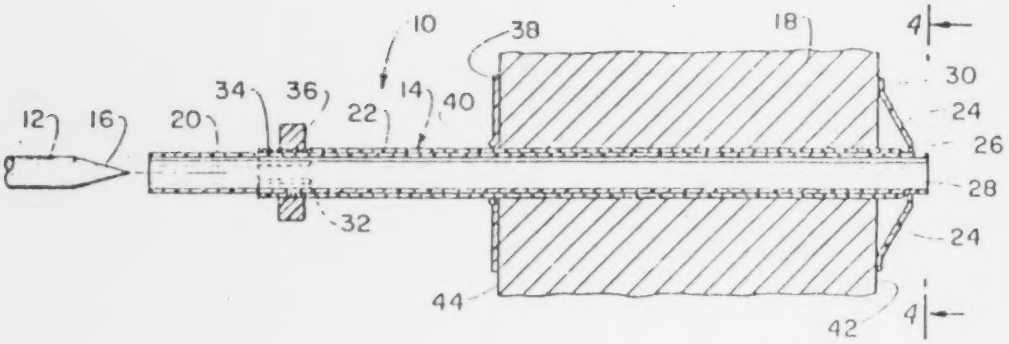
[57] ABSTRACT

A catheter apparatus for retention within the body of an animal employing a sleeve assembly composed of an inner sleeve telescopingly supported within an outer sleeve, a multiple radially expandable finger assembly hingedly integrally connected at one end to the outer sleeve and capable of being maintained in the radially outermost position by the inner sleeve, the fingers being movable substantially in line with the outer sleeve upon disassociation of the inner sleeve.

8 Claims, 6 Drawing Figures



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FLESH PENETRATING APPARATUS

BACKGROUND OF THE INVENTION

The field of this invention relates to medical devices and more particularly to a device which provides access to an interior cavity of an animal body.

In a certain area of medicine trocars are readily employed. A trocar is a sharp pointed instrument which is used to insert a cannula into a body cavity to be employed as a drainage outlet. Basically, a cannula is an elongated rigid tubular element which is to provide communication exteriorally of the body to within a cavity of the body. For example, cannulas are frequently used upon cattle to vent an animal's stomach upon it becoming bloated. Such a disease is quite common in cattle and if a vent is not provided, frequently the animal dies. Additionally, a passage which is provided by a cannula can be employed to facilitate direct insertion of medication into the stomach cavity of an animal. Further, such devices may be applied to an infected wound which requires drainage.

Although such devices are most frequently used upon the lower order of animals, there are certain instances in which a trocar and cannula can be applied to humans. The use of such an instrument in humans would be primarily toward the application of medicines within an internal cavity, such as the stomach, or to effect drainage of an infected wound.

Trocars and cannulas may be made in numerous sizes. To effect drainage of a wound a needle-like size may be adequate. However, to effect insertion of such into the stomach cavity, a pencil size (or larger) cannula may be desired. Heretofore, the trocar related to a pointed instrument which is slidably contained within the cannula. The trocar is caused to penetrate the flesh of the animal and to extend a desired depth within the animal. The trocar carries along with it the cannula. Upon the cannula reaching the desired depth, the trocar is removed leaving an open passage to the particular desired cavity within the animal. In most instances, it is desirable to leave the cannula in position for a period of time of several days. In the lower order of animals, it has not been uncommon for such located cannulas to be dislodged from position either falling exteriorly of the body or being caused to move interiorly of the body as into the stomach cavity. In the past, in an effort to prevent cannulas from moving into the stomach cavity, a portion of the cannula is enlarged and is to extend exteriorly of the body, thereby preventing such dislodgment from occurring. However, no means is provided to prevent dislodgment of the device exteriorly of the body.

In the past, trocars have been made of a stainless steel material of extremely high precision. As a result, such devices have proved most expensive, thereby making it a significant item of purchase for the veterinarian or medical doctor.

It would be desirable to design a trocar and cannula which facilitated entrance of the device interiorly of the body, such device absolutely precluding accidental dislodgment of the device once in position, and such a device being constructed simply and of a low-cost material of construction.

SUMMARY OF THE INVENTION

The apparatus of this invention may provide for the employment of a trocar which is slidably movable within a first sleeve. The trocar can be formed of either a rigid plastic or a rigid metal material with one end thereof being pointed. Basically, the trocar will be of cylindrical configuration. However, polygonal shaped configurations are not to be precluded. A second sleeve is to be located about the first sleeve which is to be of a shorter elongated length than the first sleeve. A combination of the first sleeve and the second sleeve form what is frequently called the cannula. The end of the second sleeve which is to be located within the cavity of the animal includes a plurality of radially extendable fingers. The fingers are hingedly pivoted with respect to the first sleeve and are caused to come in contact with the first sleeve upon being extended substantially at a right angle with respect to the sleeve axis. Adjacent the opposite end of the second sleeve and mounted thereupon for a sliding movement is an annular collar. The annular collar is capable of unhindered movement toward the fingers but incurs hindered movement away from the fingers. The end of the second sleeve which is to extend exteriorly of the body is externally threaded and is adapted to cooperate with a nut. This end of the second sleeve is also longitudinally slit a small amount with a plurality of equiangularly spaced apart slits. This end of the second sleeve is also tapered slightly so that upon moving a nut along the second sleeve toward the collar effects contraction of the slits and thereby a binding action to non-removably secure the second sleeve to the first sleeve. Upon the nut being moved directly adjacent the end of the second sleeve, the first sleeve is movable with respect to the second sleeve. Upon sufficient extraction of the first sleeve with respect to the second sleeve, the fingers rotate approximately 90° into substantial longitudinal alignment with the axis of the first sleeve. As a result, no tissue damage occurs during removal of the device due to the fingers being extended. The cannula may be employed without a trocar by inserting the cannula through an existing opening into a cavity. Existing openings may comprise the mouth, nose, ear, or the like. Also, existing openings may also be previous openings formed by a trocar. Further, the cannula may be inserted by a trocar which surrounds the cannula such as a hypodermic needle.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a longitudinal cross-sectional view of the apparatus of this invention showing the trocar and combined cannula during partial insertion through the tissue of an animal;

FIG. 2 is a cross-sectional view of the apparatus of FIG. 1 taken along line 2—2 of FIG. 1;

FIG. 3 is a cross-sectional view similar to FIG. 1 but showing the cannula in the retained position with the trocar being removed therefrom;

FIG. 4 is an end view of the cannula arrangement of this invention taken along line 4—4 of FIG. 3;

FIG. 5 is a fragmentary cross-sectional view showing the fingers mounted upon the second sleeve in the retracted position to facilitate removal of the cannula from the tissue; and

FIG. 6 is a view similar to FIG. 5 showing the cannula during partial removal through the tissue.

DETAILED DESCRIPTION OF THE SHOWN EMBODIMENT

Referring particularly to the drawing, there is shown in FIG. 1 the apparatus 10 of this invention broadly including a trocar 12 and a cannula assembly 14. The trocar 12 is in the general configuration of a cylindrical rod which has the pointed end 16. It is to be understood that the trocar can be made extremely small resembling a needle or can be much larger as in the shape of a pencil or the like. It is also to be understood that the trocar 12 can be in other cross-sectional configurations such as square or rectangular shape. It happens to be that the cylindrical shape depicted would be the easiest to manufacture and also would be the easiest to be inserted through the tissue 18 of the animal with minimum damage.

The trocar 12 is slidably mounted in a snug fitting manner within the first sleeve 20 of the cannula assembly 14. Telescopingly mounted about the first sleeve 20 is a second sleeve 22. Both the first sleeve 20 and the second sleeve 22 are to normally be manufactured from the same material of construction as a rigid plastic or other similar material. Also, the trocar 12 can be either a plastic or metallic material. The second sleeve 22 is of a shorter length than the first sleeve 20. The reason for the difference in length will become readily apparent further on in this specification.

Secured to one end of the second sleeve 22 is a plurality of fingers 24. Each of the fingers 24 is to be formed of a plastic material similar to the material of construction of the second sleeve 22. Each of the fingers 24 is readily disposed with respect to the second sleeve 22. It is to be noted that the number of fingers 24 is to be strictly a matter of choice or design; however, it has been found that eight in number proves to be most satisfactory.

The base of each of the fingers 24 is connected by means of a plastic hinge 26 to the second sleeve 22. Each of the plastic hinges 26 forms an integral connection with the second sleeve 22 and with its respective finger 24. The plastic hinge 26 permits pivotal movement of over 180° from the position shown in FIG. 1 of the drawing to the position shown in FIG. 6 of the drawing. Each of the fingers 24 includes a shoulder 28 adjacent the plastic hinge 26. The function of the shoulder 28 is to be described further on in this specification. Each of the fingers 24 includes a flattened foot-like area 30 adjacent its extremity. The function of the flattened area will also be described further on in this specification.

At the other end of the second sleeve 22 are located a plurality of equiangularly spaced apart longitudinal slits 32. The second sleeve 22 in the area adjacent the slits 32 is exteriorly threaded at 34. A nut 36 is adapted to cooperate with the threads 34 and be movable longitudinally upon the second sleeve 22. The second sleeve 22 in the area of the threads 34 is of a steadily increasingly circumference from the end of the second sleeve 22 to the termination of the slits 32. As a result, by tightening nut 36, a concentric contraction of the second sleeve 22 results which effects a binding action upon the first sleeve 20. This binding action is sufficient to firmly retain the second sleeve 22 together with the first sleeve 20.

Located about the second sleeve 22 nearer the nut 36 than the fingers 24 is an annular collar 38. The collar 38 is crimped at 40 in the aft direction with respect to the fingers 24. The function of the crimping 40 will also be explained further on in this specification. It is to be noted that the collar 38 is slidable about the second sleeve 22 which will also be explained in the following operation of the invention.

The operation of the apparatus 10 of this invention is as follows: It will be presumed that an animal such as a cow has become bloated in the stomach and the gas within the animal's stomach must be vented to the ambient. The veterinarian then locates the first sleeve 20 beyond the fingers 24 which are secured to the second sleeve 22. The operator then tightens nut 36 securing the sleeve 20 and 22 in this arrangement. The fingers 24 are located adjacent the exterior surface of the second sleeve 24. The trocar 12 is then inserted within the first sleeve 20. The operator then places the pointed end 16 adjacent the outer skin of the animal in the particular desired location. The operator then impacts the aft end of the trocar 12 causing the trocar 12 to penetrate the tissue 18. It is upon the penetration of the trocar 12 is to the desired depth, as in this instance to within the stomach cavity, the cannula 14 is likewise to pass through the tissue 18 until the fingers 24 entirely extend within the cavity. The operator then removes the trocar 12 providing a vent opening from the ambient to the stomach cavity by means of the passage within the first sleeve 20. The operator then grasps the exterior portion of the cannula assembly 14 and exerts a force thereupon tending to draw such from the animal. As a result, the free ends of each of the fingers 24 come into contact with the stomach wall 42 and are caused to pivot substantially 90° until the flattened areas 30 are in an abutting relationship with the wall 42. The shoulder 28 of each of the fingers 24 comes into abutting contact with the first sleeve 20 thereby preventing further pivotal movement of the fingers 24 past the 90° position. The operator can feel when this occurs because further outward movement of the assembly 14 is vigorously resisted.

The operator then moves the collar 38 along the second sleeve 22 until the collar comes into an abutting contactual relationship with the outer surface 44 of the skin of the animal. The collar 38 is then moved an additionally small amount tending to compress the tissue 18 between the collar 38 and the fingers 24. As a result, a binding action occurs between the fingers 24 and the collar 38 tending to force the crimped portion 40 into greater frictional engagement with the second sleeve 22. As a result of the foregoing, the apparatus 10 of this invention has been installed within the tissue of an animal and is to be firmly retained therein and not capable of being accidentally dislodged. Not only has a vent been provided within the stomach cavity but also a passage is provided for the direct application of medicine or other compounds.

It is to be understood that it is not necessary for the device to be inserted within an open cavity such as a stomach cavity. The apparatus could be inserted within a wound which has become infected. Upon being inserted the desired depth, the pull-back motion upon the

cannula assembly 14 would merely cause the fingers 24 to extend within the adjoining tissue. This extension of the fingers 24 will not be sufficient as to cause significant damage to the tissue. In this instance the drainage for the infected area of the wound would be provided as well as a means to apply a medication directly to the infected area.

To effect easy removal of the apparatus 10 of this invention the procedure is as follows: The operator loosens nut 36 until the first sleeve 20 can be moved relative to the second sleeve 22. Movement of the first sleeve 20 with respect to the second sleeve 22 is accomplished until the forward end of the first sleeve 20 is moved sufficiently to no longer be in cooperation with the shoulder 28 of the fingers 24. As a result, the fingers 24 are free to pivot with respect to the second sleeve 22 to the position in substantial alignment with the longitudinal axis of the second sleeve 22. Thereby as the second sleeve 22 is withdrawn from the tissue 18, the fingers 24 do not hinder the withdrawing movement.

Prior to reusage of the apparatus 10 of this invention, the fingers will be manually pivoted up against the tube 22 as shown in FIG. 1 of the drawing. Also, prior to reusage, the collar 38 is to be manually moved adjacent the threaded area 38. Movement of the collar 38 is not difficult in this direction when there is no force causing the crimped portion 40 to dig into the second sleeve 22. At this time, the apparatus 10 of this invention is ready to be reused.

Another primary advantage of the apparatus of this invention is that the cannula assembly may be employed without the use of the trocar 12. The cannula assembly 14 will be operated in a manner similar to the above described operation. However, the collar 38 may not be employed if the cannula assembly 14 is conducted a substantial distance through a natural cavity as the mouth or through a blood vessel. Actually, it is envisioned that the cannula assembly 14 may be conducted through a blood vessel and lodged in place within the heart. In such instances the inner sleeve 20 may be extended to a substantial length as well as the outer sleeve 22.

Another use contemplated for the apparatus 10 of this invention is that various measurements could be taken by liquid gauges located within the passage of the first sleeve 20. Also, each of the fingers about the flattened areas 30 could have overlapping flaps to protect the tissue in the cavity around the insertion hole. Since the cannula assembly 14 is to be made of a plastic material, it is to have no chemical reaction to tissue. Also, the cannula assembly 14 need not be constructed entirely rigid. The center portion of the cannula assembly may be flexible to facilitate curved movement of the cannula assembly 14 through a body passage (such as a blood vessel). It is only necessary for the ends of the cannula assembly to be rigid to effect operation of the fingers 24 and the nut 36. Basically the uses of the apparatus 10 of this invention are unlimited and up to the ingenuity of the operator.

I claim:

1. A catheter apparatus adapted to be inserted interiorly of an animal body, said apparatus comprising:

a first sleeve and a second sleeve, said second sleeve slidably mounted upon said first sleeve, the combined said sleeves having an inner end and an outer end, said inner end adapted to be inserted into the animal body;

a plurality of separate fingers attached to said inner end of said second sleeve, the base of each of said fingers being pivotally connected to said second sleeve, a shoulder located upon each of said fingers at its said base;

each of said finger elements being movable between a first position and a second position and a third position, the fingers in said first position being in an exterior abutting relationship and in substantial alignment with said second sleeve, said first position being the normal position of said fingers during the insertion movement of said apparatus within the animal body, said second position being such that each of said fingers is substantially perpendicular to the longitudinal axis of said second sleeve said third position being such that said fingers extend beyond said second sleeve and in substantial alignment with said axis, the shoulders being in contact with said first sleeve when the fingers are in said second position, thereby being prevented from movement toward said third position, whereby said fingers may be moved into said third position when said first sleeve is displaced interiorly of said second sleeve so that said shoulders are no longer in abutting contact with said first sleeve, whereby said fingers substantially unhinder withdrawal movement of said apparatus from said animal body.

2. The apparatus as defined in claim 1 including:

the outer extremity of each of said fingers being inclined, the inclination being such that with said fingers in said first position, said outer extremity being inclined outwardly away from said second sleeve, thereby during insertion movement of said apparatus within an animal body said inclined portion of said fingers substantially unhinder insertion movement, and upon said apparatus being completely inserted within the animal body slight movement in reverse to the insertion movement causes said inclined portions of said fingers to contact the animal body and forcibly pivot said fingers to said second position.

3. The apparatus as defined in claim 1 wherein:

each of said fingers is equiangularly spaced from each other about said second sleeve.

4. The apparatus as defined in claim 3 wherein:

each of said fingers is integrally connected to said second sleeve through a plastic hinge.

5. The apparatus as defined in claim 1 wherein:

first means adjustably located upon said second sleeve adjacent said outer end, with said fingers in said second position said first means to contact the exterior surface of the animal body to thereby effect a squeezing of the tissue of the animal between said first means and said finger assembly.

6. The apparatus as defined in claim 5 wherein:

said first means comprises a collar slidably mounted upon said second sleeve.

7. The apparatus as defined in claim 1 wherein:

said first sleeve is of a greater longitudinal length than said second sleeve.

8. The apparatus as defined in claim 1 wherein:

securing means is connected between said first sleeve and said second sleeve to fixedly retain the position of said sleeves in respect to each other.

* * * * *

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4 MONTH IN VIVO
6950 TINED ENDOCARDIAL
VENTRICULAR LEAD STUDY

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[redacted] in
[redacted] protective orders.

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DEFENDANT'S EXHIBIT
DAIG 28
NO.

DAIG EXH.
Plaintiffs Exhibit 28
Government's
Defendants Date: 1/11/83

Case No. 4-79-256 and
4-80-611

Deputy Clerk

6950 TINED ENDOCARDIAL VENTRICULAR LEAD

ANIMAL RESEARCH PERFORMANCE

FINAL REPORT

PATENTS CONFIDENTIAL

MARCH 1977

PHYSIOLOGICAL RESEARCH LABORATORY

MEDTRONIC, INC.

6950 Tined Endocardial Ventricular Lead System (Version G)

Final Report
March 1977

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AR Request #00739
AR #0064A0010
E #06950-050

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ABSTRACT

Eleven 6950 tined endocardial ventricular bipolar leads were chronically implanted in canines. The objectives of this in vivo study were to evaluate the qualities of nondislodgement, nonperforation, ease of handling and repositioning of this lead system. Stimulus thresholds, source impedances and intracardiac signal data were collected at implant and at monthly intervals up to four months for comparison to existing marketed lead systems. Due to the problems encountered with animal survival and test lead quality no recommendations regarding human implantibility of the 6950 tined endocardial lead were generated from this study.

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INTRODUCTION

A preclinical four month* study was conducted of the 6950 bipolar endocardial lead system. The request for this *in vivo* study was generated by Maria Rose of the Cardiovascular Leads Research and Engineering Department to support the claims of the 6950 lead's safety, efficacy and reliability. The 6950 lead is a redesign of the 6901 ventricular endocardial lead system. This redesign consisted of physical modification involving removal of the distal insulator flange and the addition of four 0.400" tines at 0.38" from the lead tip.[1] The tines were added in an attempt to improve the 6950 lead's dislodgement and non-perforation characteristics without sacrificing low thresholds. The tined lead was not to impact the ease of lead passage or positioning/repositioning attempts at initial implant. The electrical and mechanical specifications of the 6950 bipolar lead system are identical to those of the 6901 bipolar lead system.

Pursuant to [illegible] as provided in [illegible] Protective Orders.

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* Implant was to have been of six month duration, according to experimental design (memo #284:NF, 1976).

METHODOLOGY

Implant: Eleven 6950 leads were implanted individually in pre-conditioned mongrel dogs weighing at least seventeen kilograms. Each animal under went a right jugular venotomy. The leads were passed into the right ventricle and positioned in the apex with the aid of fluoroscopy. Attempts to perforate the myocardium were made at this point. The lead was again positioned in the apex of the right ventricle. Good lead placement was verified with threshold measurements. Initial placement, perforation attempts and repositioning were video taped (tape #'s 5, 6 and 7, 1976).

Subjects were then transferred to another operating room where the lead connector end was tunneled subcutaneously to a percutaneous threshold analyzer (PTA) that in turn was connected to an implanted 5950/5954 pulse generator by two lead extenders. The pulse generator was set at 100 bpm. The animals then underwent a right thoracotomy and were put into heartblock by electro-cautery through a purse-string incision in the right atrium.

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Threshold measurements, source impedances and cardiac signals were collected via the PTA. The pulse generator rate and pulse width were also recorded and x-rays taken of the lead/pulse generator system.

Monitoring: Monitoring was done at monthly intervals for four (4) months. The animals were prepped over the PTA, pre-anesthetized with Surital and maintained on gas inhalation. Threshold measurements, source impedances and cardiac signals were acquired via the PTA. Rate and pulse width of the implanted pulse generator were also acquired to assure proper pulse generator function.

Terminations: Following the final monitoring acquired directly from the lead connector pins, the animals were euthanatized with Sleep Away and necropsied. Any evidence of perforation or damage was noted and recorded on the Gross Pathology Data sheet. Tissue specimens were taken from the electrode sites and from a non-stimulated area of the heart for histopathologic evaluation.

RESULTS

Tables and graphs are presented of time (acute,4,8,12&16 weeks) vs. ($\bar{x} \pm SD$) of:

	table#	graph#
Source Impedances	1	1
Voltage @ Threshold	2	
unipolar configuration		2
bipolar configuration		3
Energy @ Threshold	3	
unipolar configuration		4
bipolar configuration		5

The final pathology report is divided into sections dealing with specific study objectives, comments and histopathology data:

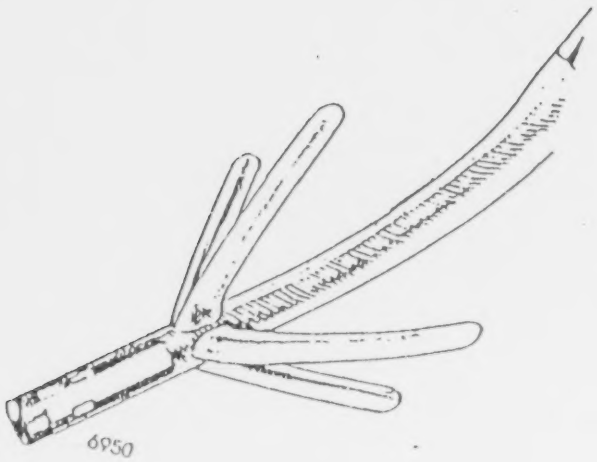
Nondislodgement
Nonperforation
Repositioning
Mechanical/Surgical Handling
AV Involvement
Pathology Summary @ Lead Site
Figure #1 Dissection of Right Ventricle
Figure #2 Cross Section of Heart
Figure #3 Cross Section Through Ventricles

The histopathology data was broken down into three groups of five animal each vs. time:

Group I study time≤6 days
Group II three weeks≤study time≤10 weeks
Group III eight weeks≤study time≤16 weeks

[illegible] Information - This [illegible] to [illegible] not [illegible] as provided in [illegible] protective order.

MEDTRONIC CONFIDENTIAL



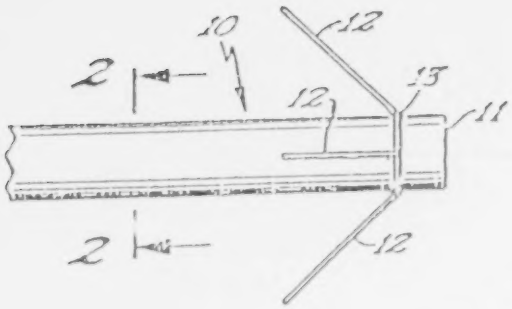
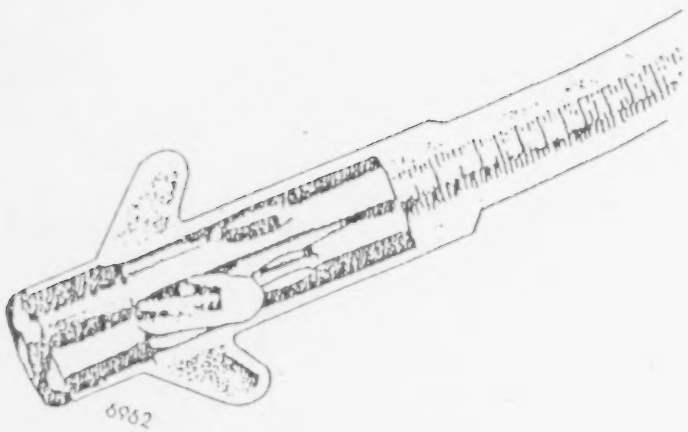
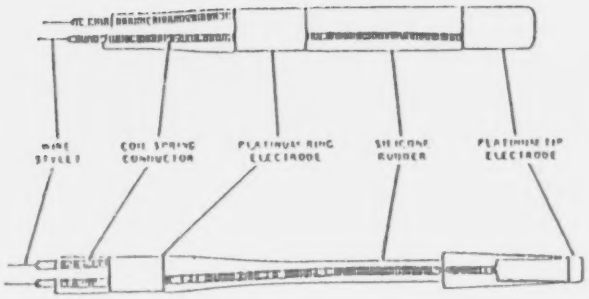


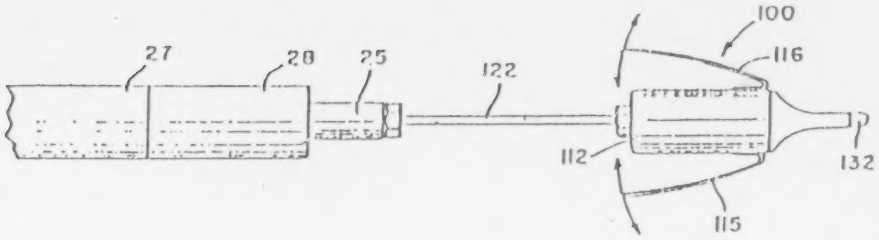
FIG. 1 OF '501 PATENT



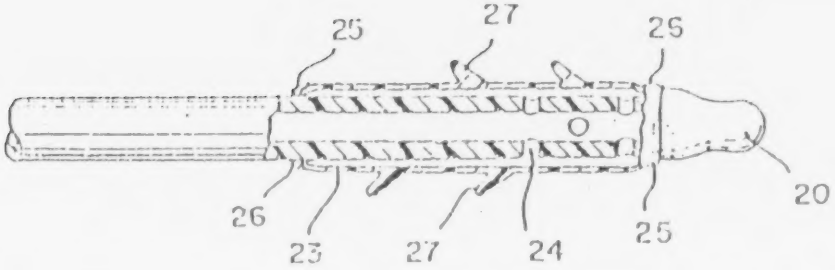
Standard tip and Flange-tip Bipolar Endocardial Leads



Nasor



Klieman



Fountain